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Counsel for KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. and the Proposed Class

[Additional counsel on signature page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated,

Plaintiff,

v.

GILEAD SCIENCES, INC., GILEAD HOLDINGS, LLC, GILEAD SCIENCES, LLC, GILEAD SCIENCES IRELAND UC, BRISTOL-MYERS SQUIBB COMPANY, E.R. SQUIBB & SONS, LLC, JAPAN TOBACCO, INC., JANSSEN R&D IRELAND, and JOHNSON & JOHNSON, INC.

Defendants.

Case No. 3:20-cv-00880

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("Plaintiff"), brings this Class Action Complaint on behalf of itself and on behalf of a Class of Direct Purchasers that purchased combination antiretroviral therapy regimen drugs during the period from May 14, 2015 until the anticompetitive effects of Defendants' conduct cease (hereinafter

referred to as "Class Period"). Defendants are Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, Gilead Sciences Ireland UC (referred to herein as "Gilead"), Bristol-Myers Squibb Company, E.R. Squibb & Sons, LLC (referred to herein as "BMS"), Japan Tobacco, Inc., Janssen R&D Ireland, and Johnson & Johnson, Inc. (referred to herein as "Janssen") (collectively referred to herein as "Defendants").

2. Combination antiretroviral therapy ("cART") regimen drugs are commonly used to treat patients with human immunodeficiency virus ("HIV"). HIV can result in Acquired Immunodeficiency Syndrome ("AIDS") and death. As further explained below, Gilead has acquired and maintained a monopoly in the market for cART regimen drugs. Gilead and its coconspirators conspired to extend patent protection for their drugs, delay entry of generic competition, and charge supracompetitive prices for cART regimen drugs.

3. Defendants' anticompetitive scheme involved engaging in unlawful contracts, combinations, and restraints of trade in the market for cART regimen drugs and unlawful monopolization in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2.

4. As a result of Defendants' anticompetitive conduct, Plaintiff and Members of a putative Direct Purchaser Class ("Class Members") paid more for cART regimen drugs than they otherwise would have paid in the absence of Defendants' unlawful conduct and sustained damages in the form of overcharges for their cART regimen drugs requirements.

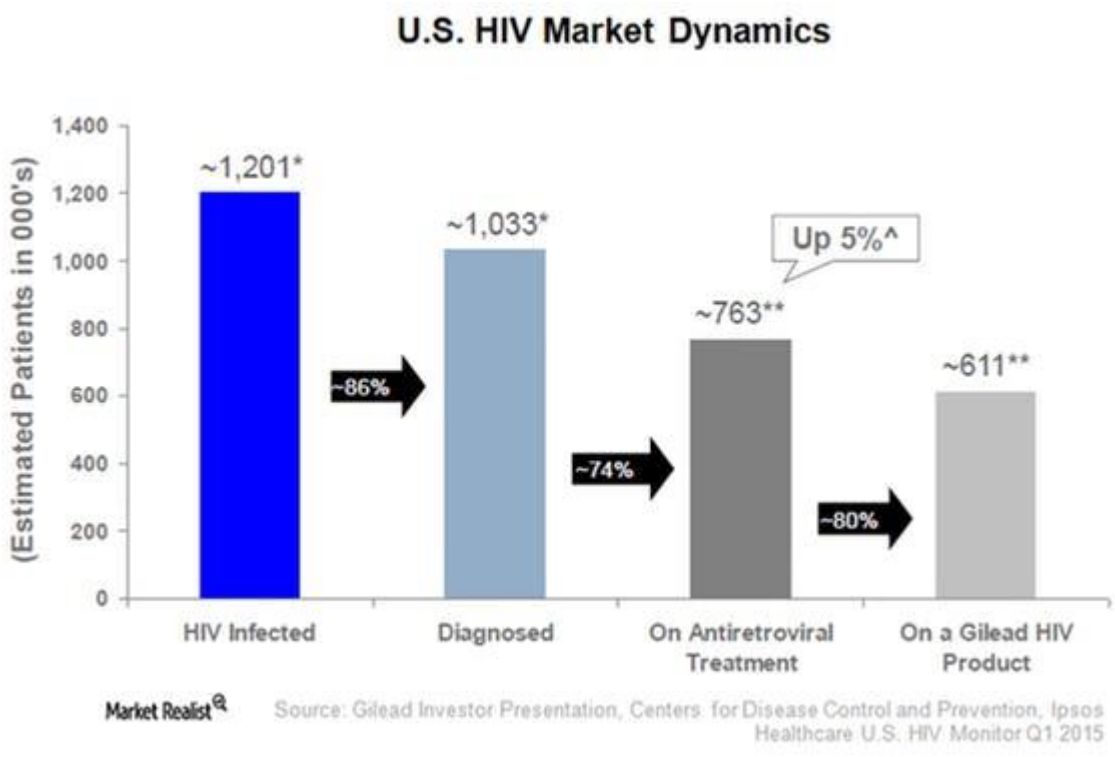
5. Plaintiff, on behalf of itself and Class Members, seeks redress for the overcharge damages sustained as a result of Defendants' violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for cART regimen drugs.

6. Plaintiff makes the allegations herein based on personal knowledge and investigation of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

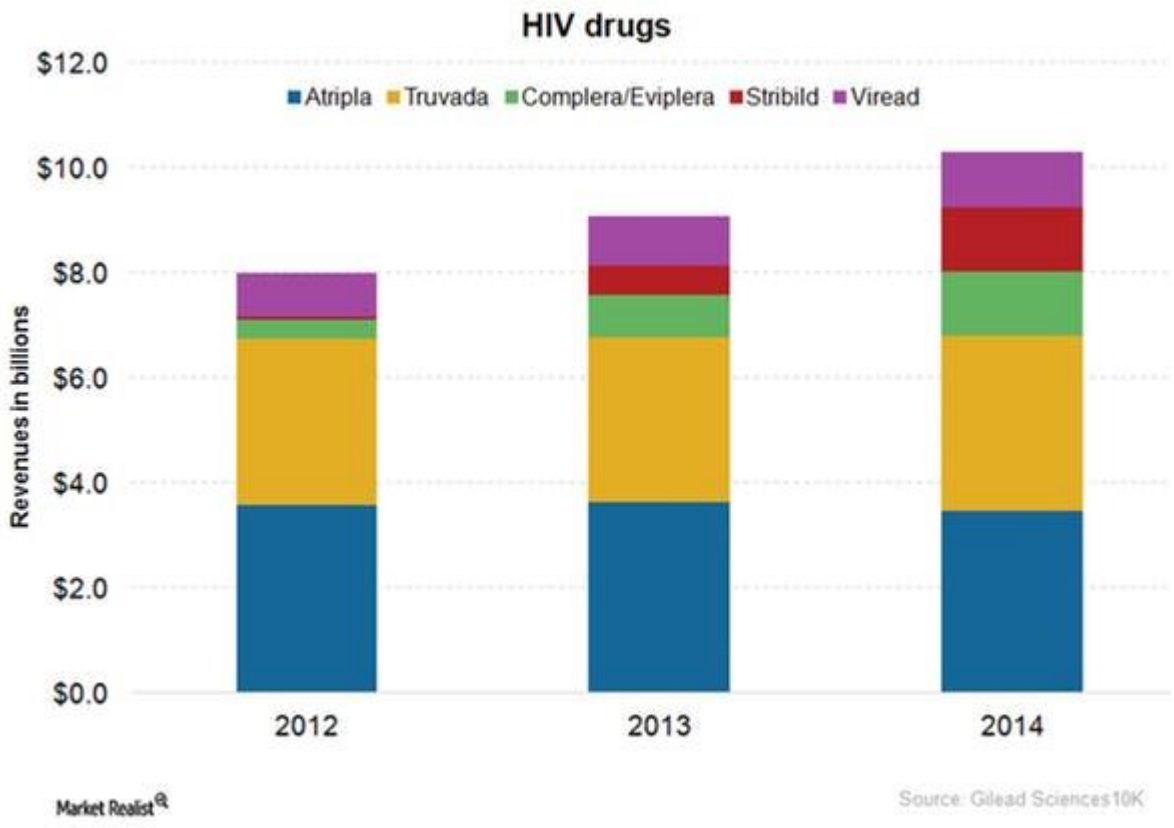
7. Modern antiretroviral cART drug regimens comprise a combination or "cocktail" of drugs, most often consisting of two nucleotide/nucleoside analogue reverse transcriptase inhibitors ("NRTIs") taken with at least one antiretroviral drug of another class, such as an integrase inhibitor, commonly referred to as "third agents." Tenofovir is one of the principal NRTIs used in cART regimens and was discovered more than 30 years ago by researchers in the Czech Republic. Gilead has long been the dominant manufacturer of Tenofovir.

8. The chart below shows that as of 2015, approximately 611,000 of the total 1.2 million HIV patients in the U.S. were using an HIV drug product marketed by Gilead[1]:



[1] *See* Margaret Patrick, *Gilead: Global Leader in the HIV Market* (August 17, 2015), available at

9. Worldwide, Gilead's total HIV revenues increased at an annualized rate of 13.4% from $8 billion in 2012 to $10.3 billion in 2014 and was due mainly to increased sales of Complera, Stribild and Viread as shown in the chart below[2]:



10. Further, Gilead dominates the market for three of the top four best-selling HIV drugs on the market, Truvada, Atripla and Stribild.[3] In 2017, Gilead earned $14 billion from its HIV pipeline.[4] Gilead has a monopoly on Truvada in the U.S. and charges between $1600 and $2000 for a one-month supply.[5] Truvada is manufactured at a cost that is a fraction of what

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https://marketrealist.com/2015/08/gilead-global-leader-hiv-market/.

[2] *Id*. (further noting that Stribild, introduced in the U.S. market in 2012, had a wholesale price of $28,500 per year in 2015).

[3] Alex Keown, *Companies Fight for Growing Share of HIV Market* (May 1, 2018), available at https://www.biospace.com/article/companies-fight-for-growing-share-of-hiv-market/.

[4] *Id*.

[5] Christopher Rowland, *An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But a Pharma Giant is Making Billions*, WASHINGTON POST (March 26, 2019), available at https://www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html.

Gilead charges in the U.S.[6] By contrast, an Indian pharmaceutical company sells generic Truvada in Africa for about $60 per year.[7]

11. In 2016, Gilead raised the wholesale acquisition cost for two of its older drugs, Complera and Stribild by 7%, or $2508 and $3469 per month, respectively.[8]

12. On March 16, 2019, Gilead raised its list process by 4.9% on "the bulk of its best-selling HIV medications."[9] Table 1 below shows Gilead's 2018 net sales from its HIV drugs:

Table 1. Gilead Net Sales for HIV Drugs 2018[10]

Drug	2018 Net Sales
Genvoya	$4.62 billion
Truvada	$3 billion
Odefsey	$1.6 billion
Descovy	$1.58 billion
Atripla	$1.21 billion
Biktarvy	$1.18 billion
Complera	$653 million
Stribild	$644 million

13. In 2001, Gilead began marketing its patented formulation of the compound tenofovir disoproxil ("TDF"). With the threat of generic competition looming as early as 2009, Gilead entered horizontal agreements with each of its coconspirators, BMS, Janssen, and Japan

[6] *Id.*
[7] Donald G. McNeil Jr., *Gilead Will Donate Truvada to U.S. for H.I.V. Prevention*, New York Times (May 9, 2019), available at https://www.nytimes.com/2019/05/09/health/gilead-truvada-hiv-aids.html.
[8] Ed Silverman, *Gilead's New Price Hikes on HIV Drugs Anger AIDS Activists* (July 5, 2016), available at https://www.statnews.com/pharmalot/2016/07/05/gilead-hiv-aids-drug-prices/.
[9] Andrew Dunn, *Gilead Raises Prices on Top-Selling HIV Treatments* (March 19, 2019), available at https://www.biopharmadive.com/news/gilead-raises-prices-on-top-selling-hiv-treatments/550733/.
[10] *Id.*

Tobacco. Under the horizontal agreements, each coconspirator agreed not to compete against Gilead's Tenofovir following expiration of Gilead's Tenofovir patents. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day.

14. Gilead and its coconspirators coformulated TDF with the coconspirators' third agents into single pills known as fixed-dose-combination drugs ("fixed dose combinations"). Each of the joint development agreements prevented the coconspirator from creating or marketing a competing version of the fixed dose combination formulated with generic versions of Gilead's TDF even after Gilead's patents expired (i.e., a "No-Generics Restraint"). Through its anticompetitive conduct, Gilead switched the market from its standalone version of TDF to the fixed dose combination. As a result, the No-Generics Restraints and joint development agreements enabled Gilead and each coconspirator to artificially inflate prices.

15. Gilead also had a booster drug, Cobicistat, which had a longer patent term. Gilead allowed BMS and Janssen to coformulate fixed dose combinations that combined their HIV drug products with Cobicistat. Gilead agreed not to market a competing fixed dose combination after BMS's and Janssen's patents expired.

16. In 2018, the horizontal agreements between Gilead and each of its coconspirators covered more than 75% of all sales of NRTIs, more than 50% of all sales of third agents, and more than 75% of all sales of booster drugs for use in a cART regimen in the United States.

17. When generic competition to TDF became imminent, Gilead amended the No-Generics pacts to preclude its coconspirators from competing against Gilead's then-marketed TDF as well as new formulation tenofovir alafenamide ("TAF"). Gilead then reformulated the original TDF-based fixed dose combination with TAF, and the reformulated fixed dose combination would not have competition until at least 2032.

18. Gilead also degraded some of its key products and held back innovative products. For example, TAF has a substantially lower incidence than TDF of significant adverse side effects. Nevertheless, in 2015, Gilead began steering patients to the TAF-based fixed dose combinations by delaying applying for FDA approval of standalone TAF for a year. Gilead's delay ensured that the new, safer version of Tenofovir was available only through purchase of a Gilead TAF-based fixed dose combination, and TAF was available only in a much higher, and less safe, dose to treat HIV. At the same time that Gilead was pursuing approval of TAF's use as a component of a Gilead fixed dose combination to treat HIV, however, Gilead sought approval of standalone TAF to treat Hepatitis B. Because Gilead failed to pursue FDA approval of standalone TAF as an HIV treatment, potential competitors were forced to perform their own time-consuming and expensive clinical trials.

19. In 2009, Teva Pharmaceuticals challenged the validity of Gilead's patents covering its NRTIs. Gilead entered a settlement with Teva that included an anticompetitive "Most Favored Entry" clause. Gilead agreed that Teva's delay in marketing its generic products would entitle Teva to an exclusivity period when Teva's generic did enter the market.

20. Gilead's delays and machinations enabled it to switch the market from TDF-based fixed dose combinations to TAF-based fixed dose combinations. Before generic competition entered the market in 2017, Gilead had switched more than 60% of its HIV product sales to the reformulated, TAF-based fixed dose combinations protected from competition by its horizontal agreements with BMS, Janssen, and Japan Tobacco.

21. In the absence of Defendants' unlawful conduct, generic versions of cART regimen drugs would have launched sooner. Competition from generics would have driven prices down to competitive levels. Plaintiff and Class Members have sustained injuries to their business and property as a result of Defendants' conduct.

22. Plaintiff brings claims for damages for Defendants' continuing violations of the Sherman Act, and Plaintiff also seeks nationwide injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

III. JURISDICTION AND VENUE

23. This Court has jurisdiction over the subject matter of this action as it arises under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Section 4 of the Clayton Act, 15 U.S.C. §§ 15(a). Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).

24. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. § 1391(b) because during the Class Period, Defendants transacted business in the United States, including in this District. Defendants transact business within this District, and the Defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the Defendants and/or their agents may be found in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

25. This Court has personal jurisdiction over Defendants because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) had and maintained substantial contacts with the United States, including in this District; and/or (c) was engaged in an unlawful scheme and conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. THE PARTIES

A. PLAINTIFF

26. Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur,

New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of McKesson Corporation, who directly purchased cART drugs from Defendants during the Class Period. As a result of Defendants' alleged anticompetitive conduct, KPH paid supracompetitive prices for its cART purchases and KPH was injured by the illegal conduct alleged herein.

B. DEFENDANTS

27. Defendant Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

28. Defendant Gilead Holdings, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Holdings, LLC is a wholly-owned subsidiary of Gilead Sciences, Inc.

29. Defendant Gilead Sciences, LLC (formerly known as Bristol-Myers Squibb & Gilead Sciences, LLC) is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead Sciences, LLC is a wholly-owned subsidiary of Gilead Sciences, Inc.

30. Defendant Gilead Sciences Ireland UC (formerly known as Gilead Sciences Limited) is an unlimited liability company organized and existing under the laws of Ireland, with a principal place of business at IDA Business & Technology Park, Carrigtohill, Co. Cork, Ireland. Gilead Sciences Ireland UC is a wholly-owned subsidiary of Gilead Sciences, Inc.

31. Gilead Sciences, Inc., Gilead Holdings, LLC, Gilead Sciences, LLC, and Gilead Sciences Ireland UC are collectively referred to herein as "Gilead."

32. Defendant Bristol-Myers Squibb Company is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 430 East 29th Street, 14th Floor, New York, NY 10016.

33. Defendant E. R. Squibb & Sons, L.L.C. is a limited liability company organized and existing under the laws of the State of Delaware, with a principal place of business at 430 East 29th Street, 14th Floor, New York, NY 10016. E. R. Squibb & Sons, L.L.C. is a wholly-owned subsidiary of Bristol-Myers Squibb Company.

34. Bristol-Myers Squibb Company and E. R. Squibb & Sons, L.L.C. are collectively referred to herein as "BMS."

35. Defendant Japan Tobacco, Inc. ("Japan Tobacco") is a corporation organized and existing under the laws of Japan, with a principal place of business at JT Building, 2-1 Toranomon, 2-chome, Minato-ku, Tokyo 105-8422, Japan.

36. Defendant Johnson & Johnson is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

37. Defendant Janssen R&D Ireland (formerly known as Tibotec Pharmaceuticals) is a private unlimited company organized and existing under the laws of Ireland, with a principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland. Janssen R&D Ireland is a subsidiary of Johnson & Johnson. Janssen R&D Ireland and Johnson & Johnson are collectively referred to herein as "Janssen."

38. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants' officers, agents, employees or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs.

V. LEGAL AND REGULATORY BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs.

39. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a) & (b).

40. When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book." Patents issued after NDA approval may be listed within 30 days of issuance. 21 U.S.C. §§ 355 (b)(1) & (c)(2).

41. A patent applicant is subject to special oaths and duties, such as the duties of disclosure, candor, and good faith, during patent prosecution. A patent applicant is required to disclose to the PTO "all information known . . . to be material to patentability" including with respect to prior art. *See* 37 C.F.R. § 1.56. This duty extends to all inventors named on a patent application and any "attorney or agent who prepares or prosecutes the application," as well as "[e]very other person who is substantively involved in the preparation or prosecution of the application." *Id*. § 1.56(c). Where fraud on the PTO "was practiced or attempted" or the duty of disclosure, candor, and good faith "was violated through bad faith or intentional misconduct" no patent should be granted. *Id*. § 1.56(a).

42. The FDA relies completely on the brand name manufacturer's truthfulness about patents' validity and applicability; the FDA has neither the authority nor the resources to check the manufacturer's representations for accuracy or trustworthiness.

B. The Hatch-Waxman Amendments Advanced the Goal of Providing Access to Generic Pharmaceuticals.

43. The Hatch-Waxman Amendments enacted in 1984 simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for the manufacturers to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A generic manufacturer seeking approval to sell a generic version of a brand name drug may now file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA but must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug – that is, that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.[11]

44. The FDCA and Hatch-Waxman Amendments operate on the presumption that bioequivalent drug products containing identical amounts of the same active ingredients in the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Thus, bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j) (8) (B).

[11] Generic manufacturers can also seek approval of non-AB-rated generics. The FDCA permits "hybrid" applications that are neither full NDAs containing safety and efficacy data, nor ANDA applications showing that the proposed product is the "same" as the NDA product. 21 U.S.C. § 505(b)(2). Drug products approved under this section use a safe and effective active pharmaceutical ingredient, but modify the drug product in some way so that it differs from the original NDA product, either in dosage form, strength, route of administration, formulation, dosing regimen, or indication. These non-AB-rated generics are not bioequivalent to the innovator product. *See* 21 C.F.R. § 314.54.

45. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of generic drugs, thereby reducing healthcare expenses nationwide. Congress also wanted to protect pharmaceutical companies' incentives to create new and innovative products.

46. The Hatch-Waxman Amendments achieved both goals, substantially advancing the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, pre-Hatch Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic versions available; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generics totaled $21.6 billion, and generic drugs accounted for 18.6% of prescriptions. By 2009, total prescription drug revenue had soared to $300 billion, and generic drugs accounted for 75% of prescriptions.

C. ANDA Patent Certifications Provide Incentives to Generic Manufacturers to Challenge Patents.

47. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand name drug has expired (a "Paragraph II certification");

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

48. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA simply by suing the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement

action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. The FDA may grant "tentative approval," but cannot authorize the generic manufacturer to go to market.

49. As an incentive to spur generic companies to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification gets a period of protection from competition with other generic versions of the drug. For Paragraph IV certifications made prior to December 2003, the first generic applicant is entitled to 180 days of market exclusivity, i.e., the first approved generic is the only available generic for at least six months.

50. Brand name manufacturers are incentivized to list patents in the Orange Book due to the high profit margins on brand name drugs and the erosion of those profits due to generic entry. Brand name manufacturers are motivated to sue any generic competitor that files an ANDA with Paragraph IV certifications even if the generic competitor's product does not actually infringe the listed patent(s) and/or the patent is invalid and unenforceable. As a result, final FDA approval of an ANDA can be delayed for up to 30 months.

D. FDA Approval Under 21 U.S.C. § 355(b)(2).

51. In addition to allowing drug manufacturers to seek expedited FDA approval under the ANDA process, the Hatch-Waxman Amendments permit streamlined approval under Section 505(b)(2) of the FD&C Act, 21 U.S.C. § 355(b)(2). In contrast to an ANDA, a Section 505(b)(2) application allows greater flexibility as to the characteristics of the proposed product, relaxing the otherwise applicable requirements that the product be in the same route of administration, dosage form, and strength as the referenced brand drug.

52. Consequently, a drug approved through the Section 505(b)(2) process will not necessarily be rated therapeutically equivalent to the referenced brand drug, and thus might not be automatically substitutable for it at the pharmacy counter. In some circumstances, however, the FDA will designate a drug approved through the Section 505(b)(2) process as AB-rated to the brand drug.

53. Like an NDA, an application under Section 505(b)(2) contains full reports of investigations of the drug's safety and effectiveness. Unlike in an NDA, however, some of the required information to establish safety and effectiveness in a Section 505(b)(2) application may come from studies not conducted by the applicant. Instead, that information may come, for example, from the FDA's finding of safety and effectiveness of the referenced brand drug or from published literature. This can result in a much less expensive and much faster route to FDA approval compared with submitting a full NDA. In essence, an application under Section 505(b)(2) is a hybrid between an NDA and an ANDA.

54. In addition to new indications and different dosage forms, routes of administration, or salts of chemical compositions, Section 505(b)(2) can be used to seek approval of new combinations of existing drugs. On a case-by-case basis, the FDA determines which clinical trials or other data the applicant will need to submit in order to get approval to market the drug.

E. New Chemical Entity Exclusivity.

55. The Hatch-Waxman Amendments provide periods of exclusivity that benefit branded pharmaceutical manufacturers. One of these periods is a 5-year new chemical entity ("NCE") exclusivity. The NCE exclusivity provision states that, where the FDA has approved a new chemical entity (a drug substance that the FDA had not previously approved), no other manufacturer may seek FDA approval for a product containing that drug substance until five years after the FDA first approved it. 21 U.S.C. § 355 (j)(5)(F)(ii) & (c)(3)(E)(ii).

56. Under the FDA's implementing regulations, if a drug product contains a new chemical entity, the FDA is precluded from accepting any ANDA or application under 21 U.S.C. § 355(b)(2) for a drug product that contains the same chemical entity until the 5-year NCE exclusivity period has expired. 21 C.F.R. § 314.108(b)(2).

57. Pursuant to the FDA's "umbrella policy," after a drug substance becomes eligible for 5-year NCE exclusivity, products subsequently developed that contain the same drug substance also benefit from the original 5-year NCE exclusivity until the original exclusivity period has expired. For example, the FDA might in year 1 approve standalone drug X, which contains new drug substance A, and grant it NCE exclusivity that expires in year 6. If the FDA later, in year 4, approves a fixed dose combination that contains composition A, then the existing NCE exclusivity also applies to the fixed dose combination and also runs until year 6.

58. An NCE exclusivity has a profound impact on the timing of generic approvals, generally precluding an applicant from even filing an ANDA for the entire 5-year NCE exclusivity life span. As an exception, the applicant may file an ANDA after the first four years of the 5-year exclusivity if the ANDA contains a Paragraph IV certification. But filing a Paragraph IV certification also subjects the ANDA to a 30-month stay of FDA approval, which does not commence until the 5-year NCE exclusivity expires. Thus, obtaining NCE exclusivity over a patent-protected drug may prevent the FDA from approving a generic applicant for as long as 7.5 years from the start the of NCE exclusivity.

F. Generic Competition Serves the Public Interest.

59. Typically, AB-rated generics cost much less than their branded counterparts. Over time, as more generic equivalents compete with each other, prices decline even further. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either

require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

60. Every link in the prescription drug chain has an incentive to choose less-expensive generic equivalents. As a result of federal reimbursement rules and the industry pricing structure, pharmacies typically earn a higher markup on generics. Private health insurers similarly offer direct incentives to pharmacies to substitute cheaper generic products for more expensive branded ones. Health insurers are contractually obligated to pay for the bulk of their members' prescriptions, whether filled with branded or generic drugs, so health insurers offer their members lower copays for generic drugs in order to encourage the use of generics. Members also face the threat of increased health insurance premiums if branded prescription drug costs continue to rise.

61. Once a generic equivalent hits the market, the generic quickly causes sales of the branded drug to diminish. More than 90% of prescriptions for drugs that are available in both branded and generic forms are filled with a generic. The speed with which generic drugs take over the market appears to be increasing: in a sample of drugs losing patent protection between 1991 and 1993, generics on average held a 44% market share after one year; by 2010, IMS industry data reflects that, on average, generics captured 80% of the brand's sales within 6 months.

62. Because of the strong potential for generics to diminish sales of brand name drugs, brand name manufacturers are motivated to extend their market dominance for as long as possible.

63. Since the passage of the Hatch-Waxman Amendments, every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and

use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing.

64. Experience and economic research demonstrates that the first generic manufacturer to launch prices its product below the price of its brand counterpart.[12] Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

65. Once additional generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other for market share, lowering prices and driving them down toward marginal manufacturing costs.[13]

66. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around 30%, but that with two generic entrants near term retail price reduction is about 50% or more.

67. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2011 FTC Study found that generics captured 80%

[12] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at ii-iii, (Aug. 2011) ("FTC 2011 AG Study"), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed June 19, 2018); FTC Pay-for-Delay Study, at 1.

[13] *See, e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, INT'L J.L. INDUS. ORG. (Aug. 2007); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

or more of sales in the first six months.[14] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, although generic drugs are clinically identical to their brand counterparts, they are typically sold at substantial discounts from the brand price. Generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

VI. FACTUAL ALLEGATIONS

A. The Development of cART Regimen Drugs.

68. The Centers for Disease Control and Prevention ("CDC") reported that in 2017, the last year for which data is available, an estimated 1.1 million people in the United States were living with HIV, nearly 40,000 people were newly diagnosed with it, and more than 5,000 deaths were attributable to HIV. If left untreated, an HIV infection generally progresses into AIDS, which prevents a patient's the immune system from fighting diseases against which the body is normally able to protect itself.

69. In 1987, the FDA approved azidothymidine ("AZT"), the first drug to treat HIV infection, but effective therapy to treat the disease was not available until 1996.

70. Two innovations led to the introduction of effective therapy for HIV. The first innovation was the development of novel classes of powerful drugs that target the HIV virus, known as "third agents" or "core agents." Protease inhibitors, introduced in 1996, were the original type of third agent. The second innovation was the discovery that an effective HIV treatment must include a combination or "cocktail" of at least two drugs (initially three or more drugs) that inhibit the viral life cycle through at least two different mechanisms of action, an approach known as "combination antiretroviral therapy" or "cART."

71. Effective cART reduces HIV viral replication to such an extent that the

[14] FTC 2011 AG Study, at 66-67.

concentration of virus (known as the "viral load") in treated patients drops to "undetectable" levels, generally defined as less than 50 RNA copies of HIV per milliliter of blood or plasma. As a result, a patient's immunologic function is greatly restored and the likelihood of transmission of HIV to others is very low. An HIV patient must continue the cART regimen for the rest of their lives. If a person stops taking a cART regimen, viral replication will soon restart, resulting in viral rebound and the resumed destruction of a patient's immune system.

72. A modern cART regimen most often consists of two drugs of the nucleotide/nucleoside analogue reverse transcriptase inhibitor ("NRTI") class, often referred to as an "NRTI backbone," taken with a third agent of another class, as shown in Tables 2 and 3.

Table 2. Active Pharmaceutical Ingredients ("API")

API (ABBREVIATION)	CLASS OF DRUG
Lamivudine (3TC)	NRTI*
Tenofovir Disoproxil Fumarate (TDF)	NRTI
Emtricitabine (FTC)	NRTI
Tenofovir Alafenamide (TAF)	NRTI
Efavirenz (EFV)	Third Agent-Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)
Rilpivirine (RPV)	Third Agent-NNRTI
Elvitegravir (EVG)	Third Agent- Integrase Strand Transfer Inhibitor (INSTI)
Atazanavir Sulfate (ATV)	Third Agent-Protease Inhibitor
Darunavir Ethanolate (DRV)	Third Agent-Protease Inhibitor
Ritonavir (RTV)	Booster

Table 2. Active Pharmaceutical Ingredients ("API")

API (ABBREVIATION)	CLASS OF DRUG
Cobicistat (COBI)	Booster

*NRTI, Nucleoside Reverse Transcriptase Inhibitor

Table 3. HIV Drug Products

DRUG NAME • NDA HOLDER • APPROVAL DATE • Abbreviation	1ST NRTI*	2ND NRTI	THIRD AGENT	BOOSTER	TYPE
Viread • Gilead • 10/26/01 • TDF	tenofovir disoproxil fumarate (TDF)	--	--	--	Standalone
Emtriva • Gilead • 7/2/03 • FTC	--	emtricitabine (FTC)	--	--	Standalone
Truvada • Gilead • 8/2/04 • TDV/FTC/EFV	tenofovir disoproxil fumarate (TDF)	emtricitabine (FTC)	efavirenz (EFV)	--	Fixed Dose Combination
Atripla • Gilead • 7/12/06 • TDF/FTC/EVF	tenofovir disoproxil fumarate (TDF)	emtricitabine (FTC)	efavirenz (EFV)	--	Single Tablet Regimen
Complera • Gilead • 7/12/06 • TDF/FTC/RPV	tenofovir disoproxil fumarate (TDF)	emtricitabine (FTC)	rilpivirine (RPV)	--	Single Tablet Regimen

Table 3. HIV Drug Products

DRUG NAME • **NDA HOLDER** • **APPROVAL DATE** • **Abbreviation**	**1ST NRTI***	**2ND NRTI**	**THIRD AGENT**	**BOOSTER**	**TYPE**
Stribild • Gilead • 8/27/12 • TDF/ETC/EVG/COBI	tenofovir disoproxil fumarate (TDF)	emtricitabine (FTC)	elvitegravir (EVG)	cobicistat (COBI)	Single Tablet Regimen
Genvoya • Gilead • 11/5/15 • TAF/FTC/EVG/COBI	tenofovir alafenamide (TAF)	emtricitabine (FTC)	elvitegravir (EVG)	cobicistat (COBI)	Single Tablet Regimen
Odefsey • Gilead • 3/1/16 • TAF/FTC/RPV	tenofovir alafenamide (TAF)	emtricitabine (FTC)	rilpivirine (RPV)	--	Single Tablet Regimen
Descovy • Gilead • 4/4/16 • TAF/FTC	tenofovir alafenamide (TAF)	emtricitabine (FTC)	--	--	Fixed Dose Combination
Vemlidy • Gilead • 11/10/16 • TAF	tenofovir alafenamide (TAF)	--	--	--	Standalone
Prezista • Janssen • 6/23/06 • DRV	--	--	darunavir ethanolate (DRV)	--	Standalone

Table 3. HIV Drug Products

DRUG NAME • **NDA HOLDER** • **APPROVAL DATE** • **Abbreviation**	**1ST NRTI***	**2ND NRTI**	**THIRD AGENT**	**BOOSTER**	**TYPE**
Revavatz • BMS • 6/20/03 • ATV	--	--	atazanavir sulfate (ATV)	--	Standalone
Evovatz • BMS • 1/29/15 • ATV/COBI	--	--	atazanavir sulfate (ATV)	cobicistat (COBI)	Fixed Dose Combination
Prezcobix • Janssen • 1/29/15 • DRV/COBI	--	--	darunavir ethanolate (DRV)	cobicistat (COBI)	Fixed Dose Combination
Edurant • Janssen • 5/20/11 • RPV	--	--	rilpivirine (RPV)	--	Standalone
Symtuza • Janssen • 7/17/18 • TAF/FTC/DRV/COBI	tenofovir alafenamide (TAF)	emtricitabine (FTC)	darunavir ethanolate (DRV)	cobicistat (COBI)	Single Tablet Regimen
Tybost • Gilead • 9/24/14 • COBI	--	--	--	cobicistat (COBI)	Standalone

*NRTI, nucleotide/nucleoside analogue reverse transcriptase inhibitor

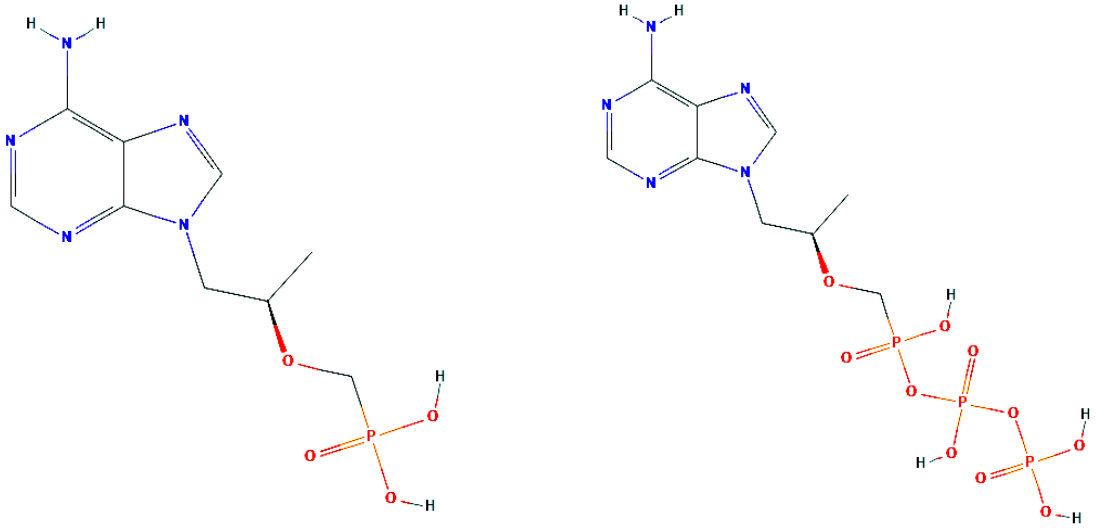
73. For example, all "first line" regimens that the United States government recommends for treatment-naïve patients, *i.e.*, those not previously treated for HIV, consist of two

NRTIs (either (i) Tenofovir with emtricitabine or lamivudine or (ii) abacavir with emtricitabine or lamivudine) taken with a third agent of the integrase strand transfer inhibitor ("INSTI") class, specifically dolutegravir, bictegravir, or raltegravir. The use of abacavir is recommended for only a select patient population and only with a particular third agent, dolutegravir.

74. Tenofovir is the most common NRTI used in cART regimens in the United States. Tenofovir is unique among NRTIs approved to treat HIV infection, in that it is a nucleotide analogue, rather than a nucleoside analogue. All NRTIs must be "activated" by the patient's cells for the drug to inhibit viral replication. This activation process is known as phosphorylation, and it comprises the chemical addition of a phosphate group to a drug molecule through specific human enzymes known as kinases. Tenofovir's dominance among NRTIs, and the need to use NRTIs in almost all cART regimens, allowed Gilead and its coconspirators to monopolize the market for cART regimens.

75. With the exception of Tenofovir, all NRTIs approved to treat HIV need to be triple phosphorylated, *i.e.*, three phosphate groups need to be sequentially added to the drug molecule for the drug to be activated. Tenofovir, however, already has a single phosphate group analogue, a phosphonate moiety, attached to the drug molecule. Thus, Tenofovir needs to be phosphorylated only twice by host enzymes to be converted into its activated form, tenofovir-diphosphate ("TFV-DP"). This allows Tenofovir to skip the slowest or "rate limiting" step in the NRTI activation process, the addition of the first phosphate group to the drug, allowing Tenofovir to have superior intracellular pharmacokinetics (fundamentally, allowing a higher concentration and longer half-life of the activated molecule (TFV-DP) in the cell). *See* Figure 1.

Figure 1. Structures of Tenofovir and Tenofovir-Diphosphate



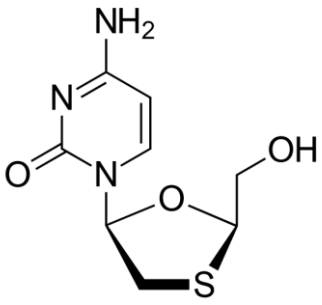
Tenofovir Tenofovir-Diphosphate (TVF-DP)

76. But the presence of a phosphonate group also comes with a distinct disadvantage: it prevents Tenofovir, by itself, from being developed as an orally administered drug. To combat this problem, Gilead developed two different "prodrugs" of Tenofovir to allow it to be swallowed. Prodrugs are pharmacologically inactive compounds that can be more efficiently absorbed and then converted into the active form of the drug within the body. Gilead markets two different Tenofovir prodrugs: tenofovir disoproxil fumarate ("TDF") and tenofovir alafenamide fumarate ("TAF").

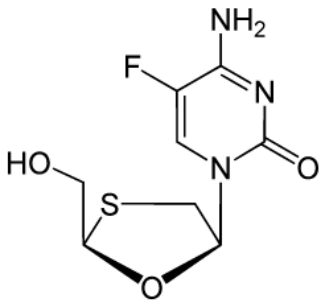
77. Tenofovir is almost always used alongside another NRTI, specifically either lamivudine ("3TC") or emtricitabine ("FTC"). *See* Table 3, *supra.* When an HIV virus becomes resistant to either 3TC or FTC, the virus's susceptibility to Tenofovir increases. Thus, the combination of Tenofovir with either 3TC or FTC makes it more difficult for the virus to develop resistance to a cART regimen.

78. 3TC and FTC are remarkably similar, varying by the substitution of only a single hydrogen atom in 3TC, with a fluorine atom in FTC in the 5-prime position of the cytosine ring. *See* Figure 2.

Figure 2. Structures of Lamivudine and Emtricitabine



Lamivudine ("3TC")



Emtricitabine ("FTC").

79. Both the United States Department of Health and Human Services ("HHS") and the World Health Organization ("WHO") guidelines stipulate that the drugs, when used for HIV treatment, can be used interchangeably. Any cART regimen using FTC can use 3TC instead, and vice versa, with no reduction in therapeutic efficacy.

80. The ability to use 3TC instead of FTC is important to the antitrust claims here. Gilead owns and currently still has patent protection for FTC, but generic 3TC has been available in the United States since 2012. When generic Tenofovir (specifically, generic TDF) became available in December 2017, the price of cART regimens should have dropped because two generic NRTIs, 3TC and TDF, were available in the marketplace.

81. The need to use multiple drugs in cART regimens can be a barrier to patient compliance. To reduce this possible burden, multiple antiretroviral drugs are often coformulated together into a single pill. These are known as "fixed-dose combinations." A fixed dose

combination that has all of the components of a complete cART regimen in a single pill is known as a "single tablet regimen" or "STR."

82. In addition to NRTIs and third agents, another class of drugs is sometimes used in cART regimens. Pharmacokinetic enhancers, commonly referred to as "boosters" (*see* Table 3), are drugs that are not taken for their anti-HIV properties, but rather for their ability to inhibit the breakdown of some third agents. Boosters work by inhibiting the liver enzymes of the Cytochrome P450 class, which break down some antiretroviral drugs. All modern protease inhibitors, as well as one integrase inhibitor, elvitegravir, are commonly used with boosters.

83. Two drugs are used as boosters, ritonavir ("RTV") and cobicistat ("COBI"). Ritonavir is an antiretroviral drug of the protease inhibitor class that can be used in lower doses as a booster alongside third agents to inhibit their breakdown. Cobicistat has no anti-HIV properties itself, but rather works just to inhibit the breakdown of other antiretroviral drugs. Gilead owns and currently still has patent protection on COBI.

B. Fixed Dose Combination Aid with Patient Compliance but Provide Ways to Exclude Generic Competition.

84. Fixed dose combinations can reduce the number of pills that patients must take, thereby possibly improving patients' compliance with their drug regimens. Gilead and its coconspirators, however, entered into a series of agreements that precluded the use of generic components instead of Gilead's products in fixed dose combinations even after its patents and regulatory exclusivities have expired.

85. Anticipating the possibility of imminent generic competition to its NRTIs – Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC) – Gilead agreed with each of BMS, Janssen, and Japan Tobacco to create and market fixed dose combinations that combined their third agents with Gilead's NRTIs. Each agreement included a No-Generics Restraint by which

BMS, Janssen, and Japan Tobacco agreed not to create or market a competing fixed dose combinations made with generic or comparable versions of Gilead's NRTIs even after the patents on them expired.

86. Gilead's patents on TDF, FTC, and TDF/FTC were weak, and as of 2004, Gilead expected to encounter generic competition to Viread (TDF), Emtriva (FTC), and Truvada (TDF/FTC) as early as 2009, 2011, and 2011, respectively, if generic manufacturers successfully challenged the patents. The Viread NCE exclusivity expired on October 26, 2006, so any 30-month stay blocking FDA approval of competing generics could have expired as early as April 26, 2009. The Emtriva and Truvada NCE exclusivities expired on July 2, 2008, so any 30-month stay blocking FDA approval of competing generics could have expired as early as January 2, 2011. Gilead's Orange-Book-listed patents would expire by their own terms in January 2018 as to Viread, September 2021 as to Emtriva, and January 2024 as to Truvada.

87. Absent the unlawful No-Generics Restraints, competitors in the position of BMS, Janssen, and Japan Tobacco would have competed against Gilead by making competing, generic containing versions of the fixed dose combinations as soon as generic TDF was available, regardless of whether generic FTC was also available. The HHS and the WHO have concluded that a very closely related drug, lamuvidine (3TC), may be substituted for FTC, and vice-versa, when used for HIV treatment.[15]

88. Generic 3TC became available in 2012. Generic TDF then became available in December 2017 and, absent Defendants' unlawful conduct, would have become available much earlier than that. Thus, competitors in the position of BMS, Japan Tobacco, and Janssen would

[15] *See, e.g.*, HHS, "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV" at F-1, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf; WHO, "Technical Update on Treatment Optimization -- Pharmacological Equivalence and Clinical Interchangeability of Lamivudine and Emtricitabine: A Review of Current Literature," https://apps.who.int/iris/bitstream/handle/10665/70936/9789241503815_eng.pdf?sequence=1.

have begun making competing versions of the fixed dose combinations in December 2017 at the latest, but for the unlawful No-Generics Restraints.

89. An industry analyst used the term "life-cycle management," to describe the scheme to extend an older product's market exclusivity beyond its patent term, which provided Gilead "a very neat get-out-of-jail card."[16]

C. Gilead and Japan Tobacco's No-Generics Restraint of Generic Entry.

90. On October 26, 2001, Gilead received FDA approval for Viread, which contains only one active pharmaceutical ingredient, TDF; on July 2, 2003, received approval for Emtriva, which contains only one active pharmaceutical ingredient, FTC; and on August 2, 2004, received approval for Truvada, a fixed dose combination containing only two active pharmaceutical ingredients, TDF and FTC.

91. In March 2005, Gilead and Japan Tobacco entered into a No-Generics Restraint pursuant to which Japan Tobacco granted to Gilead exclusive rights (even as to Japan Tobacco) to develop and commercialize elvitegravir ("EVG") in all countries of the world, excluding Japan (where Japan Tobacco retained such rights). This included an exclusive right for Gilead to make and sell in the United States any product containing EVG in combination with any other HIV drug. The agreement prevents Japan Tobacco or its licensees (except Gilead) from making and selling an EVG-containing fixed dose combination with generic TDF or generic FTC (or comparable compositions such as generic 3TC) even after the patents on TDF and/or FTC expire.

92. Under the agreement, Gilead was responsible for seeking regulatory approval in the United States and was required to use diligent efforts to commercialize a product for the treatment of HIV. Gilead bore all costs and expenses associated with the commercialization

[16] *Johnson & Johnson/Gilead Deal Could Yield More Combinations in HIV*, Seeking Alpha (June 30, 2011), available at https://seekingalpha.com/article/277464-johnson-and-johnson-gilead-deal-could-yield-more-combinations-in-hiv.

efforts. In addition, Gilead paid to Japan Tobacco an up-front license fee of $15 million and was obligated to make total potential milestone payments of up to $90 million upon the achievement of certain clinical, regulatory, and commercial objectives. Gilead was also obligated to pay royalties based on net sales.

93. Under the agreement, Gilead sets the price in the United States for products that contain EVG. The agreement, including the No-Generics Restraint and obligation to pay royalties, expires on a product-by-product basis, at the later of (1) the expiration of the last of Japan Tobacco's patents providing exclusivity for the product or (2) the ten-year anniversary of marketing the product.

94. On August 27, 2012, Gilead received FDA approval for Stribild, a fixed dose combination containing TDF, FTC, cobicistat ("COBI"), and EVG. On September 24, 2014, Gilead received FDA approval for both Vitekta, a drug whose only active ingredient is EVG, and Tybost, a drug whose only active ingredient is COBI. When Gilead and Japan Tobacco entered into their No-Generics Restraint in early 2005, Gilead expected to encounter competition from generic TDF as early as 2009. The principal patents that protected EVG, however, were not scheduled to expire until October 26, 2026. Japan Tobacco's patent claiming a fixed dose combination comprising TDF, FTC, and EVG is not scheduled to expire until April 24, 2030.

95. Thus, in or about August 2012 Gilead began to cannibalize TDF and/or FTC sales and encouraged doctors to switch their prescriptions to Stribild.

96. On November 5, 2015, Gilead received FDA approval for Genvoya, a fixed dose combination containing TAF (rather than TDF), FTC, COBI, and EVG. Gilead listed a number of patents in the Orange Book for Genvoya, including two that cover a hemifumarate form of TAF, that is, tenofovir alafenamide hemifumarate. These "Group Two" patents have an expiration date

of August 15, 2032, but they are invalid because they claim only the hemifumarate form of TAF, which is obvious in light of the prior art.

97. By the time the FDA approved Genvoya for sale, the scheduled expiration of Gilead's patents on TDF was less than 25 months away. Gilead used anticompetitive tactics, including making Stribild even less safe than its other TDF-containing drugs, to further switch the market from Stribild to Genvoya. The unlawful No-Generics Restraint protecting Genvoya from competition will not expire until April 2030.

98. After generic TDF became available in December 2017, prices should have dropped for purchasers because a competitor in Japan Tobacco's position would have competed with Gilead by marketing a fixed dose combination comprising EVG, generic TDF, generic 3TC, and generic RTV. The combined price of those products would have plummeted due to competition that should have ensued with the availability of generic TDF. That fixed dose combination would not have been subject to any NCE exclusivity, and a competitor in Japan Tobacco's position would have begun marketing it immediately upon the availability of generic RTV in March 2018.

99. A competitor in Japan Tobacco's position also would have offered a competing fixed dose combination comprising EVG and generic RTV. Such a fixed dose combination is both technologically and commercially feasible. Other manufacturers have successfully made fixed dose combinations comprising RTV and other third agents, such as lopinavir and atazanavir, and Gilead's own researchers concluded that using RTV to boost EVG results in pharmacokinetic parameters similar to those observed with COBI boosting. Such an RTV-containing fixed dose combination would not have been subject to any NCE exclusivity. This product would have competed against both Stribild and Genvoya, because patients could have taken it together with Truvada (TDF/FTC) or Descovy (TAF/FTC). A competitor in Japan Tobacco's position would

have begun marketing that product immediately upon the availability of generic RTV in March 2018.

100. A competitor in Japan Tobacco's position would have challenged Gilead's patents and entered the market with competing products even before March 2018. The NCE exclusivity on Stribild expired on August 27, 2017. Absent the No-Generics Restraint, a competitor in Japan Tobacco's position would have challenged Gilead's patents, and it would have avoided any exclusivity by obtaining from Gilead a waiver of any NCE exclusivity that Gilead might have. Japan Tobacco's leverage to obtain such a contractual avoidance of any exclusivity is illustrated by, among other indicia, its having obtained ownership of the patents on a fixed dose combination comprising TDF/FTC/EVG.

101. As a result of the unlawful No-Generics Restraint, however, purchasers will not have access to competing versions of Stribild until at least April 24, 2030 when the parties' unlawful No-Generics Restraint expires.

102. Unless enjoined by this Court, Gilead and Japan Tobacco's unlawful No-Generics Restraint will have additional anticompetitive effects when generic versions of any of FTC, TAF, or COBI become available. A competitor in Japan Tobacco's position would make additional fixed dose combinations that are substitutable for, or comparable to, Stribild and Genvoya.

D. Gilead and BMS' No-Generics Restraint.

103. In December 2004 Gilead and BMS entered into an agreement to develop and commercialize a three-active-pharmaceutical-ingredient fixed dose combination comprising Gilead's TDF and FTC, and BMS's efavirenz ("EFV"). BMS marketed EFV as a standalone product under the brand name Sustiva. At that time, Gilead expected to encounter generic competition to Viread (TDF) as early as 2009, and to Emtriva (FTC) and Truvada (TDF/FTC) as early as 2011.

104. Gilead and BMS structured the collaboration as a joint venture that operated as a limited liability company named Bristol-Myers Squibb & Gilead Sciences, LLC. Gilead and BMS granted royalty-free sublicenses to the joint venture for the use of the companies' respective technologies and, in return, were granted a license by the joint venture to use intellectual property that results from the collaboration. In 2006, the FDA approved the fixed dose combination, which Gilead and BMS marketed under the brand name Atripla.

105. Gilead and BMS initially shared marketing and sales efforts, jointly marketing the product in the United States from July 2006 through 2010. In 2011, except for a limited number of activities that were jointly managed, the parties stopped coordinating detailing and promotional activities.

106. A Joint Pricing Committee, comprising representatives of Gilead and BMS, determined the selling price of Atripla. In 2017 (before generic entry for Sustiva), the price for a 30-day supply of Truvada was approximately $1,600; the price of Sustiva was approximately $1,010; and the price of Atripla was approximately $2,600.

107. The economic interests of the joint venture held by Gilead and BMS (including share of revenues and out-of-pocket expenses) were based on the portion of the net selling price of Atripla attributable to Sustiva and Truvada.

108. The Gilead/BMS agreement provided that BMS would supply its EFV exclusively to the Gilead/BMS joint venture for use in a fixed dose combination with Gilead's TDF and FTC. The agreement thus prevented BMS and every other manufacturer from competing against Atripla with a fixed dose combinations comprising EFV and generic TDF and/or FTC, even after Gilead's patents expired. Moreover, the agreement provided that the only way for BMS to avoid this exclusivity was to terminate Gilead's participation in the joint venture and thereby have BMS become the sole entity in the venture.

109. The conspirators provided that BMS could terminate Gilead's participation in the joint venture if generic versions of both TDF and FTC became available. The agreement further provided, however, that if BMS elected to terminate Gilead's interest on that ground, BMS would be required to pay a substantial penalty to Gilead, comprising three years of additional royalty payments, at declining percentages over the three years. The purpose and effect of the penalty provision was to dissuade BMS from terminating Gilead's participation in the joint venture even after its patents on TDF and/or FTC expired.

110. The coconspirators provided to Gilead a similar right of termination, with a similar termination-penalty provision, permitting it to terminate the joint venture if a generic version of Sustiva became available.

111. In addition, either party's terminating the joint venture would terminate the other's ability to continue making and selling Atripla. Gilead and BMS thus conspired to arrange that, regardless of whether one of the coconspirators terminated the agreement once generic versions of the other's composition(s) became available, purchasers would never benefit from a marketplace in which two versions of the Atripla fixed dose combination compete against each other. If neither party terminated the agreement, both would continue to be bound by the exclusivity provision and could not make a competing generic-composition-based version of the fixed dose combination; if a party did terminate, then the other would no longer have access to the continuing party's composition(s) and could no longer make a version of Atripla.

112. When Gilead and BMS entered into their No-Generics Restraint in 2004, Gilead expected to encounter competition from generic TDF and generic TDF/FTC as early as 2009 and 2011, respectively. The principal patents that protected BMS's EFV, however, were not scheduled to expire until 2018. Although it was possible that EFV would also encounter generic competition before its patents' scheduled expiration dates, Gilead's combining its TDF/FTC with

EFV substantially increased the probability that it could shield those products from generic competition.

113. When generic TDF became available, purchasers should have benefitted because a tainted competitor in BMS's position would market a competing version of the fixed dose combination, with Gilead selling the original version of Atripla, and the competitor selling a fixed dose combination comprising generic TDF, generic FTC (once it becomes available), and EFV. The combined price of those three products would have dropped with the availability of generic TDF.

114. Absent the No-Generics Restraint, a competitor in BMS's position would have challenged Gilead's patents and entered the market with a competing fixed dose combination even before the expiration of the FTC patents in 2021. The NCE exclusivity protecting Atripla expired on July 2, 2008. Assuming that BMS were subject to that exclusivity, a competitor in its position would have challenged Gilead's patents one year before expiration of the NCE exclusivity. If Gilead timely sued BMS for patent infringement, a competitor in its position would have entered the market as early as the expiration of the 30-month stay in January 2011, on a date to be determined by the jury.

115. Gilead and BMS further conspired to protect a BMS product, atazanavir sulfate ("ATV"), from generic competition. ATV is a third agent, a protease inhibitor, that BMS markets as Reyataz. Just as the scheme used some of BMS's patents to protect Gilead's products from generic competition, so the conspirators also used some Gilead patents to protect BMS's ATV from generic competition. Gilead provided an exclusive license to BMS (exclusive even as to Gilead) to use Gilead's then-investigational new drug cobicistat (COBI) in combination with BMS's ATV.

116. On February 17, 2010, BMS received notice that generic manufacturer Teva Pharmaceuticals had submitted an ANDA with a Paragraph IV certification that the patents purportedly covering BMS's ATV were invalid and not infringed. BMS could expect to encounter generic competition to ATV (Reyataz) as early as August 17, 2012.

117. After BMS received notice of that challenge to its ATV patents, but before the generic manufacturer could enter the market, BMS and Gilead announced a deal (on October 26, 2011) to jointly develop a fixed dose combination that would combine BMS's vulnerable ATV with Gilead's COBI. Gilead and BMS expected that, as a potential new drug, COBI's patents would extend far into the future; in fact, the latest of them does not expire until September 3, 2029. On January 29, 2015, the FDA approved that fixed dose combination, which BMS markets as Evotaz.

118. The parties provided that BMS would be responsible for commercializing the fixed dose combination, and Gilead provided a No-Generics Restraint to BMS. The license from Gilead to BMS for use of COBI in the fixed dose combination is exclusive even as to Gilead, i.e., it prohibits Gilead from commercializing its own fixed dose combination that contains a generic version of ATV. Gilead is prohibited from marketing a fixed dose combination with ATV even after generic versions of it become available.

119. Under the agreement, BMS sets the price of the fixed dose combination for sales in the United States and pays a royalty to Gilead based on sales. The agreement, including the No-Generics Restraint and obligation to pay royalties, terminates after the expiration of the last of Gilead's patents providing exclusivity for COBI.

120. As contemplated by the No-Generics scheme between BMS and Gilead with respect to ATV, BMS cannibalized the sales of Reyataz by encouraging doctors to switch prescriptions from Reyataz to Evotaz.

121. Generic ATV became available in the United States in December 2017. At that time, purchasers and patients should have benefitted because: (1) doctors and patients could use generic ATV in combination with Gilead's COBI or another booster, such as generic RTV; and (2) a competitor in Gilead's position would have competed with BMS by marketing a fixed dose combination comprising generic ATV and COBI. The combined price of those products would have plummeted due to competition that should have ensued with the availability of generic ATV. The BMS/Gilead No-Generics Restraint was intended to prevent, and did in fact prevent, purchasers from obtaining those competitive benefits.

122. Absent the No-Generics Restraint, a competitor in Gilead's position would have competed with a fixed dose combination containing COBI and generic ATV as soon as possible, and it would have done so by December 2017. Under the unlawful No-Generics Restraint, however, drug purchasers will continue to be deprived of a substitutable version of Evotaz until September 2029.

123. Gilead began in August 2011 to market a fixed dose combination, Complera, and began in August 2012 to market another fixed dose combination, Stribild, that competes against Atripla. Gilead thereafter concentrated its marketing efforts in promoting those products rather than Atripla. And when Gilead began developing its line of TAF-based fixed dose combination to replace the TDF-based fixed dose combination, it did not amend the joint venture agreement with BMS to provide for the parties to commercialize a TAF-based successor to Atripla. Nor did Gilead file an application for an NDA for such a TAF-based successor product to Atripla.

124. The BMS/Gilead No-Generics Restraint with respect to Atripla prohibited BMS from making a generic version of Atripla when generic TDF and generic FTC became available but did not prohibit BMS from making a comparable version comprising generic TDF, 3TC (instead of Gilead's FTC), and EFV. When generic TDF became available, BMS licensed Mylan

Pharmaceuticals to produce that comparable version, which the FDA approved in February 2018. Mylan sells the generic TDF/3TC/EFV version of the product at a 40% discount to the price of branded Atripla.

125. Gilead recently terminated BMS's participation in the Atripla joint venture, triggering Gilead's obligation to make the penalty payments described above.

E. Gilead and Janssen's No-Generics Restraint

126. On July 16, 2009, Gilead and Janssen entered into a collaboration agreement to develop and commercialize a fixed dose combination whose active pharmaceutical ingredients would be Gilead's Truvada (TDF/FTC) and Janssen's rilpivirine ("RPV").

127. Gilead submitted an NDA for the product on February 10, 2011. On August 10, 2011, the FDA approved the NDA for Complera, the fixed dose combination containing TDF/FTC/RPV.

128. The FDA approved Janssen's Edurant, whose only active pharmaceutical ingredient is 3 RPV, on May 20, 2011.

129. Under the parties' agreement, with amendments through 2013, Janssen granted to Gilead a No-Generics Restraint for use of RPV in a fixed dose combination comprising TDF/FTC/RPV. The agreement prevents Janssen from marketing a fixed dose combination comprising generic TDF, generic FTC, and RPV. The agreement also prohibits Janssen from selling any "Other Combination Product" comparable to TDF/FTC/RPV, which precludes Janssen from selling a product made with generic TDF, 3TC (rather than FTC), and RPV.

130. The agreement provides that Gilead is responsible for manufacturing Complera and distributing and commercializing it in the United States as well as in much of the rest of the world. Janssen has the right to distribute it in other regions, including Japan and Russia.

131. Under the agreement, Gilead sets the price of Complera and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. The coconspirators agreed that in the United States the selling price of Complera would be the combined prices of Truvada (TDF/FTC) and Edurant (RPV) when sold separately. Gilead purchases RPV from Janssen for use in Complera at approximately the market price of RPV, less a specified percentage of up to 30%.

132. Janssen could not terminate the agreement until after the expiration of the last-to-expire patent for RPV.

133. Through 2011, Gilead reimbursed Janssen approximately $100 million in research and development expenses, which was the maximum amount allowed under the agreement.

134. When Gilead and Janssen entered into their No-Generics Restraint in 2009, Gilead had recently sued Teva in connection with Teva's first-to-file ANDA for Truvada. Gilead expected to encounter generic competition as early as May 2011, the end of Teva's 30-month stay. The principal patents that protected RPV, however, were not scheduled to expire until dates ranging from 2019 to 2025.

135. As contemplated by the No-Generics scheme, Gilead cannibalized TDF and/or FTC sales, encouraging doctors to switch their patients from those products to Complera.

136. The restated agreement also confirmed that the license from Janssen to Gilead was "exclusive" even as to Janssen, i.e., it prohibits Janssen from commercializing its own fixed dose combination that contains either (1) generic versions of TDF and FTC and its own RPV or (2) generic versions of TAF and FTC and its own RPV; only Gilead has the rights to fixed dose combinations with those ingredients, even after generic versions of TDF, FTC and/or TAF become available. And again, the restated agreement further prohibits Janssen from marketing any comparable product, including one made with TAF (or TDF), 3TC (rather than FTC), and RPV.

137. Gilead is responsible for manufacturing Odefsey and has the lead role in registration, distribution, and commercialization of it in the United States. Gilead sets the price of Odefsey, and the parties share revenues based on the ratio of the net selling prices of the party's component(s), subject to certain restrictions and adjustments. Gilead continues to retain a specified percentage of Janssen's share of revenues, up to 30%.

138. The agreement, including the No-Generics Restraint and the obligation to pay royalties, expires on a product-by-product basis, at the later of (1) the expiration of the last of Janssen's patents providing exclusivity for the product or (2) the ten-year anniversary of marketing the product.

139. By the time the FDA approved Odefsey for sale in March 2016, the scheduled expiration of Gilead's patents on TDF was less than 22 months away. Gilead used anticompetitive tactics, including making standalone TAF less safe, to drive patients to Odefsey, which the unlawful No-Generics Restraint protects from competition until March 25, 2026.

140. When generic versions of TDF became available in 2017, purchasers and patients should have benefitted because a competitor in Janssen's position would have competed with Gilead by marketing a competing version of Complera comprising generic TDF, 3TC, and RPV. The combined price of those products would have dropped due to the competition that should have ensued with the availability of generic TDF.

141. Absent the No-Generics Restraint, a tainted competitor in Janssen's position would have offered a competing product long before December 2017. Such a competitor would have challenged Gilead's patents. No NCE exclusivity applicable to Complera would have barred Janssen from timely seeking FDA approval for a competing fixed dose combination because Janssen controlled the NCE exclusivity. The only NCE-protected ingredient in Complera at the

time of its approval was Janssen's RPV. Janssen, not Gilead, owns the patents covering fixed dose combinations comprising TDF/FTC/RPV.

142. A competitor in Janssen's position would have submitted its own application for a product containing TDF/FTC/RPV as early as August 2011, and any 30-month stay would have expired in February 2014. Thus, a competitor in Janssen's position would have competed against Gilead with a fixed dose combination comprising RPV and generic versions of TDF and FTC as early as February 2014, on a date to be determined by the jury.

143. But the unlawful No-Generics Restraint resulted in Janssen's agreeing not to compete until at least December 9, 2025, when the No-Generics Restraint expires.

144. Likewise, absent the No-Generics Restraint, a competitor in Janssen's position would have produced and marketed a substitutable version of Odefsey as soon as possible. The NCE exclusivity that attached to TAF, and that protects Odefsey, does not expire until November 5, 2020. But a competitor in Janssen's position would have obtained from Gilead a contractual waiver of that exclusivity (Janssen's leverage to do so is illustrated by, among other things, its having obtained co-ownership of the patents on a fixed dose combination comprising TAF/FTC/RPV). Thus, a competitor in Janssen's position would have submitted its own application for a product containing RPV, generic TAF, and generic FTC as soon as the FDA approved the NDA for Odefsey. After waiting out the 30-month stay, such a competitor would have entered the market as early as September 2018.

145. In addition to their unlawful No-Generics Restraint involving RPV, Gilead and Janssen entered into mutual No-Generics promises involving Janssen's product, darunavir ("DRV"), which Janssen markets as Prezista. The agreements concerning DRV amount to a mutual nonaggression pact in which both parties could have made the fixed dose combination with generic versions of the other's compositions, but both agreed not to do so even after the

relevant patents expired.

146. In October 2010, a year after the announcement of the Complera deal, Janssen received notice that generic manufacturer Mylan Pharmaceuticals had submitted an ANDA with a Paragraph IV certification that the patents purportedly covering Janssen's Prezista (DRV) were invalid and not infringed. Janssen could expect to encounter generic competition to DRV as early as April 2013.

147. On June 28, 2011, less than nine months after receiving Mylan's notice of intention to challenge the Prezista patents, Janssen and Gilead announced a tentative deal to jointly develop a fixed dose combination that would combine Janssen's vulnerable Prezista (DRV) with Gilead's then-investigational new drug cobicistat (COBI). Gilead and Janssen expected that, as a potential new drug, COBI's patents would extend far into the future; in fact, the latest of them does not expire until September 3, 2029. The FDA ultimately approved the DRV/COBI fixed dose combination on January 29, 2015, and Janssen now markets the product as "Prezcobix."

148. Gilead and Janssen, however, had made a definitive agreement as to Prezcobix subject to reaching an even broader deal involving DRV. Their finalizing a Prezcobix deal was expressly contingent on concluding a further agreement to coformulate Janssen's DRV with Gilead's TAF, FTC, and COBI. The FDA ultimately approved that product on July 17, 2018, and Janssen now markets it as "Symtuza."

149. Without mutual No-Generics Restraints with respect to Symtuza, both Gilead and Janssen were vulnerable to generic-composition-based competition from the other. Janssen's DRV patents are weak and can easily be designed around. Thus, absent Gilead's giving a No-Generics Restraint to Janssen, a competitor in Gilead's position would begin in 2021 (at the latest) to market a competing version of Symtuza comprising generic DRV and Gilead's TAF,

FTC, and COBI.

150. Absent Janssen's giving a No-Generics Restraint to Gilead, Janssen could have begun in July 2018 marketing a fixed dose combination that would compete with Symtuza, comprising DRV and generic RTV. Patients could take that DRV/generic RTV pill together with a fixed dose combination comprising generic TDF/3TC. Janssen could also begin competing in May 2023 with an additional comparable fixed dose combination, comprising generic TAF, generic 3TC, generic RTV, and DRV.

151. Gilead and Janssen entered into their mutual nonaggression pact in which each provided a No-Generics Restraint to the other. Janssen agreed with respect to DRV, just as it had with respect to RPV, not to produce or market a competing version of the fixed dose combination with compositions that were either generic versions of, or comparable to, Gilead's compositions even after the relevant Gilead patents have expired. Likewise, Gilead agreed that it would not produce a competing fixed dose combination comprising generic DRV and Gilead's TAF, FTC, and COBI, even after Janssen's patents on DRV expired.

152. Gilead and Janssen entered into the Symtuza deal on December 29, 2014. The same day, and in the same document, Gilead and Janssen finalized their agreement regarding Prezcobix. Also, on the same day, Gilead and Janssen amended their Complera agreement to include Odefsey. The three deals for Complera/Odefsey, Prezcobix, and Symtuza are part of a single conspiracy in which both Janssen and Gilead unlawfully refrain from competing against the other's vulnerable-to-competition compositions, even after the relevant patents expire.

153. The agreement regarding Prezcobix and Symtuza provides that Janssen is responsible for marketing the products in the United States. The agreement also provides that: (1) Janssen sets the price of Prezcobix and Symtuza; (2) the price will be the combined price of each of the separate compositions; (3) the parties split the revenues based on the ratio of the net selling

prices of the party's component(s); and (4) the agreement, including the No-Generics Restraints, terminates at the later of the expiration of the last of either party's patents providing exclusivity for the product or the ten-year anniversary of marketing the product.

154. As contemplated by the No-Generics scheme, Janssen began in the first quarter of 2015 to cannibalize the sales of Prezista by encouraging doctors to switch prescriptions from Prezista to Prezcobix and, later, to Symtuza. As of 2017, Janssen had succeeded in shifting at least 40% of Prezista prescriptions to Prezcobix.

155. After generic TDF became available (December 2017), generic RTV became available (March 2018), and the FDA approved Symtuza (July 2018), purchasers and patients should have benefitted because a competitor in Janssen's position would have competed with Symtuza by marketing a fixed dose combination comprising DRV and generic RTV, which patients could take together with a pill comprising generic TDF/3TC. Alternatively, patients could have taken the DRV/generic RTV pill together with Descovy (TAF/FTC). The combined price of those products would have dropped due to competition that should have ensued with the availability of generic TDF and generic RTV.

156. Absent the No-Generics Restraint, a competitor in Gilead's position would have competed with a substitutable version of Prezcobix as soon as possible. No unexpired NCE exclusivity protected Prezcobix from competition from Gilead. A competitor in Gilead's position would have filed an application for such a product by January 2015, and, after waiting out the 30-month stay, would have begun marketing it by July 2017. By that date, the only non-expired Orange Book patents owned by Janssen were those covering certain pseudopolymorphic forms of DRV, which expire on February 16, 2024 and December 26, 2026 (assuming no pediatric exclusivity is later awarded). Those patents are invalid and can easily be designed around.

157. Absent this Court's intervention, drug purchasers will continue to be deprived of a

substitutable version of Prezcobix until at least January 2025 when the parties' unlawful No-Generics Restraint with respect to Prezcobix expires.

158. Unless enjoined by this Court, Gilead and Janssen's unlawful No-Generics Restraints will have additional anticompetitive effects when generic versions of the following become available: FTC, DRV, TAF, or COBI. But for the unlawful No-Generics Restraints, a competitor in Janssen's position would produce and market fixed dose combinations that are substitutable for, or comparable to, Complera, Odefsey, and Symtuza. But for the unlawful No-Generics Restraints, a competitor in Gilead's position would produce and market fixed dose combinations that are substitutable for, or comparable to, Prezcobix and Symtuza.

F. Effects of the No-Generics Restraints – Increased Prices.

159. Gilead's agreements with BMS, Janssen, and Japan Tobacco provided several means for Gilead's coconspirators to share in the supracompetitive profits that the unlawful No-Generics Restraints generated. The restraints substantially increased Gilead's incentive to move sales from TDF and/or FTC to the TDF-based fixed dose combinations. Those switched sales resulted in the coconspirators' selling significantly more of their third agents than they otherwise would have. The restraints also significantly dampened competition in the cART Market, generating higher prices for the fixed dose combinations and therefore for the conspirators' third agents. And Gilead directly paid the coconspirators through the royalty and other provisions of the joint-development agreements. For example, Gilead paid Janssen a $100 million fee under their original agreement.

160. Likewise, the No-Generics Restraints made no economic sense for Gilead unless they impaired competition. Those restraints did not benefit Gilead in the period of time before it lost statutory exclusivity (exclusivity from its patents or from NCE exclusivity); during that time Gilead already had exclusivity and no one could make a competing fixed dose combinations that

contained Gilead's exclusivity-protected products. Gilead benefitted from the No-Generics Restraints only during the period after its statutory exclusivity expired.

161. Defendants' anticompetitive conduct (1) artificially reduced the prescription base of Gilead's Viread (TDF), Emtriva (FTC), and/or Truvada (TDF/FTC) available for automatic generic substitution, much of that prescription base having been cannibalized to the TDF-based fixed dose combinations; (2) deprived purchasers of competing fixed dose combinations made with generic or comparable versions of those products; and (3) impaired price competition in the cART Market.

162. Defendants' anticompetitive schemes exploited the tendency of doctors who have switched patients from one HIV product or HIV drug regimen to another to be reluctant to switch patients back to the original product or regimen, even if a generic version of the original product becomes available at a much lower price. Brand manufacturers can also deter imminent generic competition by using their sales force to cannibalize the sales of the brand drug before the generic enters the market.

163. Gilead and its coconspirators switched much of the prescription base from TDF and/or FTC to the TDF-based fixed dose combinations (Atripla, Stribild, and Complera). Generic versions of TDF and/or FTC are not AB-rated to, and therefore not automatically substitutable for, the TDF-based fixed dose combinations. Automatic substitution at the pharmacy counter is a generic product's most efficient means of competing. Gilead and the coconspirators' switching of the prescription base from TDF and/or FTC to the TDF-based fixed dose combinations thus impaired the only effective means for standalone generic products to compete. The No-Generics Restraints prevent Gilead's coconspirators from making competing versions of the fixed dose combinations with generic or comparable versions of TDF and/or FTC.

164. Depending on the competing manufacturer's regulatory strategy, generic-drug-

containing versions of the fixed dose combinations could be approved under the ANDA process of Section 505(j) of the FD&C Act (21 U.S.C. § 355(j)), and the resulting product would be automatically substitutable at the pharmacy counter for the original version of the fixed dose combinations. Or the competing manufacturer could gain approval under Section 505(b)(2) of the FD&C Act (21 U.S.C. § 355(b)(2)). Under either regulatory strategy, the competing generic-drug-containing versions of the fixed dose combinations would sell at very substantial discounts to the price of the original fixed dose combinations.

165. Absent the No-Generics Restraints' anticompetitive effects, competitors in the position of BMS, Janssen, and Japan Tobacco would have begun making the fixed dose combinations with generic or comparable versions of TDF and/or FTC as soon as they became available. Making the fixed dose combinations with low-cost generic ingredients would have resulted in those manufacturers' lowering the price of the fixed dose combinations and thereby increasing sales, while still maintaining at least the same profit margin.

166. The No-Generics Restraints thus artificially inflated prices of those standalone components, of the fixed dose combinations, and of other products in the cART Market that Gilead and its coconspirators have unlawfully monopolized. fixed dose combinations that are originally formulated with a generic composition and a brand composition sell for about 40% - 50% less than the combined prices of the brand versions of the two compositions. As a result of the No-Generics Restraints, the Defendants' fixed dose combinations continue to sell for about 100% of the combined prices of the brand components, even after the relevant patents expire and generic components are available.

167. Similarly, when fixed dose combinations made with comparable (but not substitutable) compositions enters the market and competes against the incumbent fixed dose combination, the competitor's price is about 40% - 50% less than the incumbent's price. As a

result of the No-Generics Restraints, however, comparable versions of all but one of the affected fixed dose combinations here (Atripla being the exception) are not available. For example, the Gilead/Janssen fixed dose combination Complera (TDF/FTC/RPV) sells for $35,000 for a yearly course of treatment. A comparable version made with generic or comparable versions of Gilead's components (generic TDF and generic 3TC) and Janssen's RPV would sell for half that amount.

168. Gilead, Janssen, and BMS moved sales from their standalone products to the fixed dose combinations that they had unlawfully protected with No-Generics Restraints. Those switches ensured that drug purchasers would not get the typical 80% price discounts on generic versions of the standalone products. The No-Generics Restraints ensured that purchasers would not get those price discounts indirectly through lower pricing of generic-drug-based versions of the fixed dose combinations.

169. The No-Generics Restraints also delayed the dates that generic drugs became available. The restraints reduced the incentives of generic manufacturers to challenge the patents protecting the fixed dose combinations (including those protecting the individual components). Absent the No-Generics Restraints, a generic manufacturer could assemble a substitutable version of the fixed dose combinations by: (1) successfully challenging the patents on one of the coconspirator's compositions and obtaining a license from the other coconspirator to use its product in the fixed dose combinations; or (2) successfully challenging the patents on both of the coconspirators' compositions. The No-Generics Restraints eliminated the first possibility, forcing generic manufacturers into an all-or-nothing venture to succeed against the patents on all of the compositions. The No-Generics Restraints thus created formidable entry barriers to those seeking to compete against the fixed dose combination.

170. Absent the No-Generics Restraints, competitors in the position of Japan Tobacco, BMS, and Janssen (either directly themselves or through a collaboration with a generic

manufacturer) would have challenged Gilead's patents in order to make generic-drug-containing versions of the fixed dose combination. The revised No-Generic Restraints prevent Japan Tobacco and Janssen from making generic-TAF-containing versions of the TAF-based fixed dose combination. Those amended unlawful restraints extend to as late as 2032.

G. Effects of the No-Generics Restraints – Decreased Innovation.

171. The No-Generics Restraints directly prohibit competitors from developing and marketing more than two dozen identifiable fixed dose combinations. Further, the No-Generics Restraints caused Gilead to intentionally delay developing products and deliberately degrade the safety and efficacy of the products that it did develop.

172. Reducing "pill burden" is an important goal in cART regimens. Those regimens, by definition, require patients to take multiple drugs to treat HIV, and before the development of fixed dose combinations required patients to take a separate pill for each drug in their regimens. Fixed dose combinations reduced this pill burden significantly, often allowing a patient to take just a single pill once a day to effectively treat HIV.

173. Because of the effects of its anticompetitive conduct, Gilead had no incentive to innovate. Gilead and its coconspirators' No-Generics Restraints have suppressed innovation by Gilead's competitors, directly and expressly prohibiting them from producing and marketing fixed dose combinations. Defendants' conduct has prevented competitors from developing at least 28 specifically identifiable fixed dose combinations. Absent Defendants' unlawful conduct, the cART Market would have about twice as many fixed dose combinations as are now available. Defendants' unlawful conduct has delayed or prevented the development and marketing of at least the following fixed dose combinations and other HIV drugs: genericTDF/genericFTC/RPV; genericTAF/genericFTC/RPV; TAF/FTC/COBI/genericDRV; COBI/genericDRV; genericTDF/3TC/genericCOBI/DRV; genericTDF/genericFTC/genericCOBI/DRV;

genericTAF/3TC/RTV/DRV; genericTAF/genericFTC/genericCOBI/RTV; genericTAF/genericFTC/genericCOBI/genericRTV; DRV/genericRTV; TDF(reduced dosage)/FTC/COBI/EVG; genericTDF(reduced dosage)/genericFTC/genericCOBI/EVG; genericTDF/genericFTC/genericCOBI/EVG; genericTAF/genericFTC/genericCOBI/EVG; genericTDF/genericFTC/EFV; COBI/genericATV; genericTDF/3TC/RPV; genericTAF/3TC/RPV; genericRTV/EVG; genericTDF/3TC/EVG; genericTAF/3TC/EVG; TDF/FTC/Dolutegravir; TDF/3TC/Dolutegravir; TAF/FTC/Dolutegravir; TAF/3TC/Dolutegravir; genericTDF/genericFTC; genericTDF/genericFTC/genericATV; TAF/FTC; TAF 10mg; generic TAF 10mg; TAF indicated for HIV treatment; generic TAF indicated for HIV treatment; generic TDF; generic FTC.

174. Gilead and its coconspirators' unlawful conduct also has dampened Gilead's own incentive to innovate. The unlawful conduct has substantially diminished the competitive pressures that force manufacturers to introduce better products sooner. The No-Generics Restraints shielded Gilead from those competitive pressures, with predictable consequences: Gilead produced markedly inferior products and chose to delay introducing improved products until it had wrung as much profit as possible out of the substandard ones. The No-Generics Restraints prevented the market from forcing Gilead to do what suppliers in competitive markets must do in order to thrive—market better products as soon as possible.

175. Defendants' No-Generics Restraints allowed Gilead to make profits not principally by innovating, but by impairing competition. This reality is seen in two stark facts: (1) from 2004 through 2017 Gilead generated more than $59 billion in revenue from its HIV franchise in the United States; (2) in that same timeframe, Gilead developed exactly one new pharmaceutical compound—COBI. And even COBI did not debut until 2014, is merely a booster, and has a close substitute in RTV. Gilead has one of the worst innovation track records of any major

pharmaceutical manufacturer anywhere in the world. Rather than innovate, Gilead used the No-Generics Restraints and other anticompetitive tactics to continually wring profits out of the two compositions—TDF and TAF—that it developed more than 15 years ago.

176. The No-Generics Restraints created the incentive and ability for Gilead to delay introducing the improved TAF products much earlier than 2015.

H. No-Generics Restraints Delayed TAF in 2003-2004.

177. Gilead knew at least by 2001 that TAF created significantly less risk of side effects. Compared to TDF, far smaller doses of TAF deliver equal or greater concentrations of Tenofovir in the cells that HIV targets. A 25 mg dose of TAF has the same therapeutic effect as a 300 mg dose of TDF. TAF therefore has far less risk of toxicity and side effects, especially kidney toxicity and bone density loss.

178. TDF and TAF are two different prodrugs of Tenofovir. Gilead scientists began research on TAF as a potential avenue for reducing kidney and bone side effects as early as 2000. Early Gilead studies in animals showed that TAF had 1,000-fold greater activity than TDF against HIV.

179. In 2002 Gilead conducted clinical trials of TAF in humans, with the explicit goal, as articulated by Gilead's senior executive, of "deliver[ing] a more potent version of tenofovir that can be taken in lower doses, resulting in better antiviral activity and fewer side effects…."[17]

180. In 2003 Gilead reported to investors regarding the TAF clinical trials that the "[i]nitial data look promising," and that Gilead was "excited" about TAF's prospects. In January 2004 Gilead again reported to investors that the TAF results were "promising," and that it was "continuing the clinical development of [TAF] … based on favorable Phase I/II results." In March

[17] *Special Coverage: 9th Conference on Retroviruses – New drugs, new data hold promise for next decade of HIV treatment*, AIDS Alert (May 1, 2002), https://www.reliasmedia.com/articles/76107-special-coverage-9th-conference-on-retroviruses-new-drugs-new-data-hold-promise-for-next-decade-of-hiv-treatment.

2004 Gilead reported that "[b]ased on data from our Phase 1/2 clinical trials of [TAF], we have begun developing a Phase 2 program for the treatment of HIV infection…."[18]

181. In May 2004, Gilead reported that the TAF clinical studies had confirmed that TAF gets higher concentrations of Tenofovir into the blood than does TDF, thus allowing the patient to take a far smaller dose, thereby significantly reducing the risk of negative side effects. Gilead told investors that "we know that doses of [TAF], which are 1/6 or 1/2 of the [TDF] dose, can give greater antiviral response. So, the theory holds that you can target and treat HIV differently using these kinds of prodrug and targeting technologies."

182. Gilead continued to praise TAF to investors through at least June 2004.

183. On October 21, 2004, however, Gilead abruptly announced that it had changed course and decided to shelve further development of TAF. The announcement attributed the decision to "an internal business review."[19] In fact, Gilead had concluded that it could use No-Generics Restraints in fixed dose combinations to shield TDF and TDF-based products from competition and therefore could safely shelve the TAF project to use much later as part of an anti-generic strategy once competition from generic TDF was imminent.

184. On December 17, 2004, Gilead formally entered into the unlawful No-Generics Restraint with BMS for Atripla. Gilead's December 2004 Press Release noted that Gilead and BMS's joint work on developing the project had "been ongoing throughout most of 2004."[20] In October 2004, the same month that Gilead announced the shelving of its TAF project, the coconspirators announced favorable results from an ongoing clinical trial of Atripla.

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[18] Gilead Sciences, Inc., 2003 Annual Report (Form 10-K), at 7 (Mar. 10, 2004).

[19] Melody Petersen, *Patients sue Gilead, saying drug company intentionally delayed safer HIV medicine*, Los Angeles Times (May 9, 2018), available at https://www.latimes.com/business/la-fi-gilead-hiv-drug-lawsuit-20180509-story.html.

[20] Press Release, Gilead, *Bristol-Myers Squibb and Gilead Sciences Establish U.S. Joint Venture to Develop and Commercialize Fixed-Dose Combination of Three HIV Medicines: First Collaboration to Develop a Once-Daily Antiretroviral Fixed-Dose Regimen* (Dec. 20, 2004), available at https://www.gilead.com/news-and-press/press-room/press-releases/2004/12/bristolmyers-squibb-and-gilead-sciences-establish-us-joint-venture-to-develop-and-commercialize-fixeddose-combination-of-three-hiv-medicines.

185. Throughout 2004 Gilead also had been negotiating and finalizing a No-Generics Restraint with Japan Tobacco. Three months after entering the BMS No-Generics Restraint, Gilead entered a No-Generics Restraint with Japan Tobacco. Gilead then proceeded with shelving the TAF project.

186. At an investor conference in March 2011, Kevin Young, the executive vice president of Gilead's commercial operations, admitted that in 2004 Gilead "didn't bring TAF through development because at the time we were launching Truvada, launching Atripla…."

187. Despite having allegedly abandoned TAF research in 2004, Gilead in fact filed seven applications for patents on TAF from 2004 to 2005. Six years later, when it was finally time to prepare for the TAF-based line extension, Gilead told investors in 2010 that "a new molecule" would replace its TDF-based sales and add "a great deal of longevity" to its HIV franchise. In fact, the "new molecule" was the TAF molecule that had been shelved by Gilead to introduce later when needed in the line extension.

188. As part of the line extension, Gilead told investors, doctors, and patients that TAF was superior to TDF. In October 2010, Gilead told investors that "you can take a lower dose [of TAF], and actually our clinical study would indicate 1/6th to 1/10th the Viread dose and you would actually get higher efficacy with less exposure." However, Gilead's statements were based on the 2003 clinical study, not any new study or data.

189. Similarly, in March 2011 Gilead's then-COO, John Milligan, told investors that "even at low doses of 50 milligram, [TAF] is a more potent antiviral than Viread." TAF provided "lower exposure [of Tenofovir] to the rest of the body. So, the therapeutic index goes up by about 34, which is pretty dramatic." Gilead's statements were based on the 2003 studies.

190. On May 3, 2011, Milligan confirmed why Gilead had sat on TAF for more than 10 years. Holding TAF in reserve to later reformulate the TDF-based fixed dose combination would

"bring quite a bit of longevity to the Gilead portfolio," securing an "important opportunity for Gilead long-term." It allowed Gilead to "have another wave of single tablets."

191. COO Milligan admitted to analysts and others in June 2011 that the plan was to transition the TDF-based franchise to a "new" TAF-based franchise. Gilead was specifically using the switch to defeat generic competition: "our ability to develop and get [the TAF-based products] onto the market prior to patent expiration will be key to us, to maintain the longevity."[21]

192. Gilead consistently and aggressively presented doctors with head-to-head comparisons of TDF versus TAF with respect to kidney function and bone density. Gilead then followed the presentations with direct appeals for doctors to switch to the TAF-based products. For example, Gilead stated at a major doctors' conference that TDF "has been associated with an increased risk of [chronic kidney disease]," whereas "[d]ue to a 91% lower plasma tenofovir level, [TAF] relative to TDF has demonstrated a significantly better renal safety profile…." At another major conference Gilead told the assembled doctors that "[s]witching from TDF to TAF may be an important treatment strategy to increase bone mineral density in those at the highest fracture risk." Gilead instructed its "detailers"—the sales force that calls on individual doctors—to make the same pitch regarding the "new" TAF. Gilead also marketed the superiority of TAF-based products directly to patients, and Gilead made the same case to clinical investigators and to the FDA when Gilead sought approval of the TAF-based products.

193. Advising its investors of its marketing message, Gilead stated, "if you're a new patient, start with a TAF-based single-tablet regimen, because that's going to be highly efficacious and very safe and very tolerable for long-term usage. And if you're on a Viread-based regimen, it's a great idea to convert, switch, upgrade to a TAF-based regimen as soon as possible."

[21] Gilead Sciences, Inc. at Goldman Sachs Global Health Conference – Final, FD (Fair Disclosure) Wire (June 7, 2011).

194. Mr. Milligan characterized the switch of prescriptions to its TAF-based fixed dose combination, Genvoya, as the most successful launch of an HIV product in history and concluded that the success resulted from the "very strong medical rationale for TAF versus [TDF]," and doctors' consequent "desire to move patients from a TDF containing regimen to a TAF containing regimen."[22]

195. Gilead's failure to bring TAF to the market was devastating for patients. From 2006 to 2015 tens of thousands of HIV patients using Gilead's TDF-based products unnecessarily suffered life-impairing kidney and bone side effects. Gilead itself later sponsored research that concluded that forcing patients to take TDF-based rather than TAF-based products could result in more than 16,000 excess deaths and 150,000 excess kidney, bone, and renal injuries over a nine-year period.[23]

196. Defendants' unlawful conduct also caused a delay in the ability of generic manufacturers and other competitors to challenge Gilead's TAF-related patents. NCE exclusivity prohibits a generic manufacturer from even filing an ANDA with respect to the branded product until a year before the end of the NCE exclusivity. Moreover, the Hatch-Waxman automatic 30-month stay does not commence until after the five-year NCE exclusivity expires. A generic version of an NCE-protected drug cannot realistically launch until at least 7.5 years after the brand manufacturer first receives approval of the NCE-protected drug.

197. Gilead's delay in marketing its TAF-based fixed dose combination pushed back the date on which generic manufacturers can challenge those products' patents. For example, the NCE exclusivity on Genvoya prohibits a generic manufacturer from filing an ANDA until November 5, 2019, one year before the expiration of the NCE exclusivity. Gilead will timely sue

[22] Gilead Sciences, Inc. at Barclays Global Healthcare Conference – Final, FD (Fair Disclosure) Wire (Mar. 15, 2016).
[23] *See Am J Manag Care.* 2018;24 (Spec. Issue No. 8): SP322-SP328.

the generic manufacturers, with the result that the Hatch-Waxman automatic 30-month stay will prevent generic entry until May 5, 2023 at the earliest.

198. If Defendants' No-Generics Restraints had not resulted in Gilead's delay in marketing TAF, these dates would have been much earlier. If Gilead had not shelved TAF development, a manufacturer in its position would have begun marketing TAF and TAF-based fixed dose combination not later than 2007.

199. Instead of the NCE protection for the TAF-based products (Vimlidy, Descovy, Genvoya, Odefsey, and Symtuza) expiring in November 2020, and the Hatch-Waxman 30-month stays expiring in May 2023, the NCE exclusivity protecting those products would have expired in November 2011, and the Hatch-Waxman 30-month stays would have expired in May 2013.

I. Gilead Fails to Pursue Innovative Intergrase Inhibitor Dolutegravir.

200. Dolutegravir is a third agent, an integrase inhibitor, originally owned by Shionogi Inc. and later by ViiV Healthcare.[24] In 2012 a fixed dose combination comprising TDF (and, later, TAF), FTC, and Dolutegravir would have been state-of-the-art and the best available single-tablet regimen for HIV patients at that time.

201. Gilead instead obtained FDA approval to market a fixed dose combination using TDF, FTC, COBI, and Japan Tobacco's EVG, known as Stribild. A fixed dose combination comprising TDF/FTC/Dolutegravir would have been markedly superior to Stribild. Among other things, Stribild requires a booster, COBI, in order to make EVG effective in a single dose. Gilead knew at the time, however, that COBI also has the effect of boosting TDF and thereby intensifying its risk of negative side effects, including kidney toxicity and loss of bone density. Dolutegravir does not require a boosting agent, and a fixed dose combination made with it rather than EVG would not have had the magnitude of side effects caused by Stribild.

[24] Viiv Healthcare was formed in 2009 by a partnership with GSK and Pfizer; Shionogi joined the partnership in 2012. *See Who We Are*, ViiV Healthcare, https://www.viivhealthcare.com/en-gb/about-us/who-we-are/.

202. Even disregarding negative side effects, Dolutegravir has a significant advantage as a third agent as compared to EVG, because it has a higher genetic barrier to resistance. In other words, HIV has more difficulty evolving resistance to Dolutegravir compared to EVG. Thus, Dolutegravir's efficacy is preserved for some strains of HIV that are resistant to EVG.

203. The anticompetitive incentives created by the No-Generics Restraints prompted Gilead to create a fixed dose combination formulated with the inferior third agent, EVG. With the No-Generics Restraint covering Stribild, Gilead would make a substantial portion of profits simply by impairing generic competition regardless of the relative efficacy of EVG as compared to Dolutegravir.

204. Unlike Japan Tobacco, ViiV would not have given Gilead a No-Generics Restraint. ViiV owned 3TC as well as Dolutegravir, so it would be able to make a competing version of the fixed dose combination as soon as generic TDF became available.

205. Gilead could have chosen to create a superior TDF/FTC/Dolutegravir product in 2012. However, Gilead chose to make the inferior Stribild.

206. ViiV ultimately created its own fixed dose combination using Dolutegravir as the third agent, without access to Gilead's TDF (and, later TAF) and FTC. ViiV now markets that product as Triumeq, comprising abacavir, 3TC, and Dolutegravir.

207. Recognizing the medical superiority of Dolutegravir, Gilead searched for a manufacturer of Dolutegravir who would not make a Tenofovir/3TC/Dolutegravir fixed dose combination with generic Tenofovir once it became available. Gilead eventually manufactured such a product itself. On February 7, 2018, the FDA approved a Gilead fixed dose combination comprising TAF, FTC, and Bictegravir, an integrase inhibitor that Gilead produces itself. In an ongoing patent-infringement lawsuit, ViiV alleges that Gilead's Bictegravir is merely a copy of

Dolutegravir.[25]

J. Gilead Degraded the Safety and Efficacy of Its Products.

208. Gilead intentionally degraded Stribild. Gilead knew when seeking FDA approval of Stribild that Tenofovir in a regimen boosted with COBI increased the probability of adverse side effects, but Gilead refused to reduce the strength of TDF in Stribild to account for the booster. Gilead did so in order to magnify the safety differences between TDF-based Stribild and its anticipated replacement product, TAF-based Genvoya. When formulating Genvoya, Gilead did reduce the strength of TAF to account for the booster.

209. Gilead also intentionally delayed seeking FDA approval to market standalone TAF (Vemlidy), withholding it from the market from November 2015 to November 2016. In addition, Gilead intentionally did not seek FDA approval to market standalone TAF in a safer milligram strength (10 mg), while seeking and receiving that approval only for TAF used in Gilead's fixed dose combination. Gilead also intentionally did not seek FDA approval for use of standalone TAF in the treatment of HIV (instead getting only an indication for treatment of Hepatitis B), while seeking and obtaining an HIV indication for all of the TAF-based fixed dose combination.

210. Gilead's acts to intentionally and substantially degrade Stribild and standalone TAF made economic sense for Gilead, because it impaired competition in the cART Market. The No-Generics Restraints incentivized and enabled that anticompetitive conduct.

K. Gilead Degraded Stribild.

211. As part of its scheme to move its TDF-based fixed dose combination to TAF-based fixed dose combination, Gilead intentionally refused to reduce the toxicity of TDF-based Stribild. Making Stribild less safe than the other TDF products would help Gilead to later move prescriptions from TDF-based Stribild to TAF-based Genvoya.

[25] *ViiV Healthcare Company, et al v. Gilead Sciences, Inc.,* 1:18-cv-00224-CFC-CJB (D. Del. 2018)

212. Gilead knew before it began marketing Viread that co-administering TDF with a pharmacokinetic "booster" such as RTV very substantially increased the concentrations of Tenofovir in the patient's blood. Gilead also knew that this increased exposure to Tenofovir concomitantly increased the patient's risk of severe side effects, including kidney disorders and bone-density loss.

213. Stribild is comprised of EVG, FTC, and TDF, plus the booster COBI. Gilead's own clinical trials on Stribild showed that it was even more toxic than unboosted TDF, resulting in more adverse events and treatment discontinuations. Gilead nevertheless formulated Stribild with 300 mg of TDF together with the pharmacokinetic booster COBI. This is the same dosage in which Gilead sold TDF as a standalone product, i.e., for use without a booster.

214. At the same time that Gilead was formulating TDF-based Stribild, Gilead was conducting Phase I studies of TAF. Gilead knew from those studies that COBI, like RTV, significantly increased the patient's exposure to Tenofovir and thereby substantially increased the risk of significant kidney and bone side effects. A Phase I TAF dosing trial showed that TAF 25 mg was the optimal dose to achieve activity similar to a 300 mg dose of TDF.

215. Based on that study and others, Gilead significantly reduced the dosage of TAF when formulating Genvoya from 25 mg for standalone TAF to only 10 mg in the COBI-boosted Genvoya. Likewise, when later formulating COBI-boosted Symtuza, Gilead again used TAF 10mg rather than TAF 25 mg.

216. Despite having the results of the TAF studies, Gilead sought FDA approval of COBI-boosted Stribild with 300 mg of TDF (the equivalent of 25 mg of TAF) instead of reducing the dose of TDF. With the No-Generics Restraints with Japan Tobacco in place, Gilead intended to transition the Stribild prescription base to Genvoya. Making Stribild less safe than its other TDF drugs would help Gilead transition the prescription base from Stribild to Genvoya, which

was protected by the longer No-Generics Restraint.

217. Gilead artificially increased Stribild's price. Since first marketing Stribild in 2012, Gilead had consistently made price increases on the drug once a year, in the range of 5% to 7%, which was the product's profit-maximizing price level. In connection with the switch to TAF-based Genvoya in 2016, however, Gilead took its usual annual price increase on Stribild plus another mid-year price increase of an additional 7%. The price increase boosted the wholesale price of a 12-month supply of Stribild to $34,686, substantially higher than the $30,930 price of Genvoya.

L. Gilead Degrades Standalone TAF.

218. As part of its unlawful scheme, Gilead also intentionally degraded standalone TAF. From November 2015 to November 2016, Gilead made TAF available only as a component of its fixed dose combination, not as a standalone product. During that time, when Gilead was aggressively moving prescriptions from the TDF-based products to its new line of TAF-based products, doctors could not prescribe standalone TAF together with HIV drugs manufactured by Gilead's competitors in the cART Market. Any patient who wanted TAF could get it only by buying a Gilead fixed dose combination. Gilead thus used its control over Tenofovir to impair competition from suppliers of 3TC, RTV, substitute third agents, and substitute fixed dose combination.

219. After Gilead belatedly made standalone TAF available, Gilead sold it only in 25 mg strength while making TAF available in 10 mg strength when purchased as part of a Gilead fixed dose combination. When TAF is taken concurrently with a "booster" drug (such as COBI or RTV), it is safer to take only 10 mg rather than 25 mg of TAF. By refusing to make TAF 10 mg available as a standalone product, Gilead forced the many patients who need a booster drug to buy the Gilead fixed dose combination rather than TAF plus a competing third agent.

220. Gilead achieved the same anticompetitive result by refusing to seek from the FDA approval of standalone TAF for use in the treatment of HIV. Gilead instead sought approval of the standalone drug for use only in the treatment of chronic Hepatitis B. TAF can only be used in an approved regimen for treatment of HIV by purchasing one of Gilead's fixed dose combinations.

221. Tenofovir is an essential input in a cART regimen, and Gilead has control over Tenofovir. TDF carries a substantial risk of severe side effects such as kidney toxicity and bone-density loss. TAF has a significantly better side effects profile.

222. In 2014, Gilead began applying for FDA approval for TAF-based fixed dose combination. On November 5, 2014, Gilead filed NDA 207561 for Genvoya (TAF/FTC/EVG/COBI); on June 1, 2015 filed NDA 208351 for Odefsey (TAF/FTC/RPV); and on April 7, 2015 filed NDA 208215 for Descovy (TAF/FTC).

223. At that time, Gilead did not apply for FDA approval of a standalone TAF product. Instead, Gilead intentionally delayed filing its application for that FDA approval, withholding the application until January 11, 2016. Gilead knew that by intentionally delaying the application for standalone TAF by one year, the FDA would not grant approval to market standalone TAF until about a year after approving Gilead's TAF-based fixed dose combination.

224. The FDA approved Genvoya, the TAF-based analogue to Gilead's TDF-based fixed dose combination Stribild, on November 5, 2015. Gilead then immediately began marketing Genvoya and cannibalizing the sales of Stribild (as well as Viread, Truvada, and Atripla) to Genvoya.

225. The FDA approved Odefsey, the TAF-based analogue to Gilead's TDF-based fixed dose combination Complera, on March 1, 2016. Gilead then immediately began marketing Odefsey and cannibalizing the sales of Complera (as well as Viread, Truvada, and Atripla) to Odefsey.

226. Additionally, the FDA approved Descovy, the TAF-based analogue to Gilead's TDF-based fixed dose combination Truvada, on April 4, 2016. Gilead then immediately began marketing Descovy and cannibalizing the sales of Truvada and Viread to Descovy.

227. As Gilead intended, the FDA did not approve Vemlidy, Gilead's TAF standalone pill, until November 10, 2016, just over a year after approving Genvoya. By then, Gilead had succeeded in converting more than half of all Stribild prescriptions to Genvoya, and of Complera prescriptions to Odefsey. Gilead's pattern of cannibalizing sales continued through 2018.

228. Gilead intentionally withheld standalone TAF from the market in the critical timeframe of November 2015 to November 2016. Had Gilead not done so, doctors and patients could have begun using standalone TAF in combination with other HIV drugs marketed by Gilead's competitors, rather than getting switched from their existing regimens to a Gilead TAF-based fixed dose combination. For example, widely used prescribing guidelines suggest that doctors and patients use Tenofovir in combination with (1) Gilead's FTC or generic 3TC; and (2) Japan Tobacco's EVG or ViiV's dolutegravir or Merck's raltegravir.

229. By withholding Vemlidy from the market while moving the TDF-based prescription bases to the TAF-based fixed dose combination, Gilead used its control over Tenofovir to impair competition and maintain a dominant position in the cART Market. Without a standalone TAF on the market, Gilead forced anyone who wanted to buy TAF to also buy a Gilead TAF-based fixed dose combination. Gilead's fixed dose combination were unlawfully protected from competition by the amended and broader No-Generics Restraints.

230. As part of the same anticompetitive scheme, Gilead has continued to refuse to make TAF available in 10 mg strength as either a standalone product or a fixed dose combination coformulated with FTC. In the United States, Gilead makes both standalone TAF and Descovy (TAF/FTC) only formulated with 25 mg of TAF rather than 10 mg.

231. Genvoya and Stribild contain three of the same active ingredients (FTC, COBI, and EVG), while Stribild contains TDF and Genvoya contains TAF. COBI, a pharmacokinetic "booster" drug, increases the time that a component, EVG, stays in a patient's system (i.e., the drug's pharmacokinetic "half-life"). This allows patients to take Stribild or Genvoya once a day, rather than twice a day. COBI, however, also increases the concentration of Tenofovir in the patient's blood. Thus, a patient taking Tenofovir with COBI will have a higher plasma concentration of Tenofovir than a patient who takes an equal dose of Tenofovir without COBI. This is true regardless of whether the Tenofovir is TDF or TAF.

232. Gilead knew from its long experience with Stribild that the presence of a booster drug such as COBI significantly increases the probability that Tenofovir will be more toxic to the patient's kidneys and bones. Gilead knew when formulating its TAF-based products that: (1) TAF, like TDF, has higher levels of toxicity when used together with a booster; and (2) when used together with a booster TAF would be effective at a dosage of just 10 mg. Thus, when formulating its new line of TAF-based products, Gilead included only 10 mg of TAF in its fixed dose combination, Genvoya, which contains COBI. Similarly, when coformulating TAF, FTC, and COBI together with Janssen's DRV (marketed as Symtuza beginning in July 2018), Gilead also used 10 mg rather than 25 mg of TAF. Gilead formulated all of its other TAF-based products that did not have a booster with 25 mg of TAF.

233. Despite this knowledge, Gilead chose to make both Vemlidy (standalone TAF) and Descovy (TAF plus FTC) available only with 25 mg of TAF. Gilead knew that, if Vemlidy and Descovy were available with a dosage of 10 mg of TAF, many doctors and patients would prefer to prescribe or take Vemlidy or Descovy together with a booster other than Gilead's COBI and a non-Gilead third agent, rather than Gilead's Genvoya (and, later, Symtuza).

234. The purpose and effect of Gilead's making 10 mg TAF available only in its own

boosted fixed dose combination was to force patients who want to avoid the increased risk of TAF when used with a booster to purchase the Gilead fixed dose combination. For example, a patient must purchase Genvoya rather than Descovy plus generic ATV plus generic RTV.

235. However, Gilead markets two versions of Descovy, one with 25 mg of TAF and another with 10 mg in other countries, including Japan, Canada, and European countries. The official prescribing information for Descovy from the European Medicines Agency, the regulatory agency covering all European Union countries, where the 10 mg dose is available, makes clear that the doctor should prescribe the 10 mg version, rather than the 25 mg version, when also prescribing a booster. Authorities in these nations recommend that patients take the TAF 10 mg version of Descovy as part of a boosted regimen and take the TAF 25 mg version when not used as part of a boosted regimen.

236. Gilead similarly used its control over Tenofovir to impair competition in the cART Market by refusing to seek from the FDA an indication for use of standalone TAF in the treatment of HIV. Instead, Gilead sought FDA approval only for use in treatment of chronic Hepatitis B.

237. Gilead obviously knew that standalone TAF was active against HIV, as demonstrated by Gilead's having sought FDA approval of HIV indications for numerous TAF-containing fixed dose combinations. In connection with its November 5, 2014 application for approval of Genvoya, Gilead performed and submitted to FDA studies demonstrating the efficacy of both standalone TAF and TAF/FTC in the treatment of HIV. FDA approval of standalone TAF for treatment of HIV would have required, at most, that Gilead submit some bioequivalence data that would have been trivial and inexpensive for Gilead to obtain.

238. Gilead nevertheless chose not to seek an HIV indication for standalone TAF. As in Gilead's intentional delay in marketing TAF as a standalone product at all, and in its intentional

refusal to make TAF available as a 10 mg pill, the purpose and effect of Gilead's continuing refusal to seek and obtain FDA approval for use of standalone TAF in the treatment of HIV is to force patients to purchase Gilead's fixed dose combination rather than standalone TAF plus a competing HIV drug.

239. Gilead knew that if standalone TAF (Vemlidy) were indicated for use in treatment of HIV, many doctors and patients would prefer Vemlidy together with other competing HIV drugs, rather than Gilead's TAF-based fixed dose combination. Those TAF-based fixed dose combination are indicated for use in the treatment of HIV. If doctors or patients want to use TAF that is indicated for use in the treatment of HIV, they must purchase one of Gilead's TAF-based fixed dose combination. Most doctors will not prescribe Vemlidy "off-label" for use in the treatment of HIV.

240. The patents protecting the TAF molecule are set to expire in 2022. However, Gilead has applied for patents that claim the formulation of TAF with FTC. *See, e.g.*, United States Patent Application Publication 2018/0177734 A1. If granted, those patents will extend far beyond 2022.

241. Withholding an HIV indication made economic sense for Gilead only because it impaired competition. Gilead in fact had already conducted the clinical trials necessary to get FDA approval for use of standalone TAF in treating HIV.

242. Absent the intended effect of impairing and delaying competition, degrading standalone TAF would have been economically irrational for Gilead. Notably, Gilead marketed other TAF-containing products in 2015-2016, made TAF 10 mg strength available in its fixed dose combination that were to be boosted, and obtained an HIV indication for all of its other five TAF-containing products.

243. If Gilead had not degraded standalone TAF, Gilead would have made more than an

additional $200 million in standalone TAF sales annually. Gilead's forgoing more than $200 million in additional annual TAF sales makes economic sense for Gilead solely because that conduct impairs and delays competition in the cART Market.

244. Gilead's degrading of standalone TAF was a significant departure from Gilead's longstanding practice. Gilead first acquired the rights to Tenofovir in the early 1990s. To allow oral administration of Tenofovir, Gilead formulated prodrugs of Tenofovir, thus allowing it to be marketed in the form of a pill that patients can swallow. Immediately upon marketing that form of Tenofovir (TDF) in 2001, Gilead made it available as a standalone product and obtained FDA approval for its use in treatment of HIV.

245. Gilead continued this pattern when it began marketing Tenofovir-based fixed dose combination, beginning with Truvada in August 2004. At that time, TDF was the form of Tenofovir that Gilead used in its own fixed dose combination; it used the same milligram strength in Truvada that it made available in its standalone Tenofovir (Viread); and it continued to make available for use in the treatment of HIV the same form of Tenofovir that it used in its fixed dose combination. Gilead continued this pattern without interruption throughout the introduction and marketing of all of its other fixed dose combination from 2004 through 2014.

246. Gilead has consistently cannibalized the sales of Viread (TDF) to the unlawfully protected TDF-based fixed dose combination, but Gilead made the same TDF that it used in its fixed dose combination available for purchase as a standalone drug. Shortly after Gilead began marketing Tenofovir as a standalone product (Viread), doctors began to co-prescribe and co-administer it as a "backbone" drug for use with third agents. When developing and designing their third agents, Gilead's competitors relied on reasonable access to the best available form of Tenofovir as a backbone drug, with the same form, strength, and indications as the Tenofovir that Gilead used in its own fixed dose combination. Gilead thus profited from Tenofovir's use both by

selling it as an ingredient in its fixed dose combination and by permitting competitors to market their third agents to be co-administered with the same form, strength, and indications of Tenofovir that Gilead used in its fixed dose combination.

247. To even further impair competition in the cART Market, Gilead began degrading standalone TAF in 2015. Gilead has never offered a public justification for its conduct in degrading standalone TAF, and it has no legitimate justification.

248. Through its long-standing, voluntary course of dealing with its competitors, Gilead permitted and facilitated the use of Tenofovir as a principal component of the cART regimen and caused its competitors to anticipate and rely upon access to the best available form of Tenofovir, and the form that Gilead uses in its own fixed dose combination, just as those competitors made the best forms of their third agents available for co-administration with Tenofovir. As a result, Gilead has a duty not to degrade standalone TAF for the purpose of denying its rivals the ability to continue to "interoperate" practically with Tenofovir.

249. Gilead refused to sell standalone TAF in 2015-16 and continues to refuse to sell standalone TAF in 10 mg strength and with an HIV indication. Gilead degraded standalone TAF in order to shift consumer demand for that product to Gilead's TAF-based fixed dose combination.

250. In degrading standalone TAF while making non-degraded TAF available as a component of the Gilead fixed dose combination, Gilead granted to purchasers of those fixed dose combination a bundled discount that its rivals cannot match. Gilead's conduct impaired competition from other companies who make less than all of the components in Gilead's exclusionary bundles, i.e., its TAF-based fixed dose combination.

251. Gilead's degrading TAF also artificially reduced the prescription base of Vemlidy (standalone TAF) and Descovy (TAF plus FTC) that will be available for generic substitution

when the principal patents on TAF and FTC expire in May 2022 and September 2023, respectively. Those artificial reductions in the prescription bases will: (1) dramatically increase the prices that patients will pay for TAF; and (2) reduce the pricing pressure that Gilead's TAF-based fixed dose combination would otherwise face in the cART Market. Gilead's conduct harmed competition on the merits, increased prices, limited the quality and availability of products, and increased costs.

M. Gilead's Conduct Results in Regulatory Barriers for TAF-HIV and Generic-TAF-Based Fixed Dose Combinations.

252. Gilead's intentionally withholding an HIV indication from standalone TAF caused regulatory barriers to the timely and effective entry into the market of generic standalone TAF with an HIV indication ("TAF-HIV") and generic-TAF-based fixed dose combination. Unless enjoined by this Court, Gilead will succeed in preventing competition and fixed dose combination innovation until as late as 2032. But for Gilead's anticompetitive conduct, competition should begin no later than May 2023.

253. Gilead has unlawfully manipulated the regulatory framework in order to impair and delay generic-TAF-based competition. Gilead is unlawfully maintaining its monopoly by refusing to get an HIV indication for Vemlidy (standalone TAF). Gilead's purpose in withholding an HIV indication is to force competitors seeking to market generic TAF-HIV or seeking to use it as a component of competing fixed dose combination to conduct time-consuming and expensive clinical trials.

254. But for Gilead's gaming of the regulatory system, it would be entirely unnecessary for competitors to conduct those expensive and delay-inducing trials. Gilead has already conducted the clinical trials that are necessary for FDA approval of use of Vemlidy in treating HIV. However, Gilead refused to ask the FDA for that indication, causing a regulatory barrier to competitors' entry.

255. If generic TAF was available by May 2023, doctors and patients would have important competitive alternatives to Gilead's TAF-based fixed dose combination. For example, doctors could begin prescribing generic TAF-HIV together with another NRTI (e.g., 3TC), and a third agent. Competing manufacturers could coformulate generic TAF-HIV with a large variety of antiretroviral agents to make fixed dose combination for use in the treatment of HIV.

256. Withholding an HIV indication for Vemlidy makes economic sense for Gilead only because of its anticompetitive effects, including impairing and delaying competition from generic-TAF-based competitors. Thus, Gilead is maintaining its monopoly in the cART Market.

N. TAF Faces Generic Competition by May 2023.

257. Absent Gilead's unlawful manipulation of the regulatory framework, generic TAF-HIV could enter the market by May 2023 at the latest. Gilead has NCE exclusivity for standalone TAF, which expires on November 5, 2020. That exclusivity prevents any manufacturer from filing an application with the FDA to make generic TAF until November 5, 2019. When manufacturers file such an application, Gilead will sue them for patent infringement, beginning the 30-month stay under the Hatch-Waxman Act. That stay will not begin to run until November 5, 2020 and will expire 30 months later, in or about May 2023. Absent Gilead's unlawful manipulation, manufacturers could easily "design around" Gilead's patents, get FDA approval, and begin marketing generic TAF-HIV, and use generic TAF as a component of a competing fixed dose combination, no later than May 2023.

258. Gilead's patents protecting TAF can be divided into two groups as shown Tables 4a and 4b.

Table 4a. Gilead's TAF Patents – Group One			
Patent No.	**Patent Title**	**Expiration Date**	**Description**
7,390,791	Prodrugs of phosphonate nucleotide analogues	5/7/22	Tenofovir Alafenamide Molecule
7,803,789	Prodrugs of phosphonate nucleotide analogues	2/2/22	Tenofovir Alafenamide Molecule

Table 4b. Gilead's TAF Patents – Group Two			
Patent No.	**Patent Title**	**Expiration Date**	**Description**
8,754,065	Tenofovir Alafenamide hemifumarate	8/15/32	Hemifumarate salt
9,296,769	Tenofovir Alafenamide hemifumarate	8/15/32	Hemifumarate salt

259. The first group consists of United States Patents Nos. 7,390,791 and 7,803,788, which claim the basic prodrug molecule design, or the drug composition and drug product, and which expire in 2022.

260. The second group consists of United States Patents Nos. 8,754,065 and 9,296,769, which claim the hemifumarate salt of tenofovir alafenamide, i.e., the salt in which the ratio of fumaric acid to tenofovir alafenamide is approximately 0.5, and protect that salt's use in pharmaceutical compositions. The hemifumarate salt is variously referred to as "GS-7340-03" or "TAF fumarate." These patents expire in 2032.

261. Manufacturers commonly use salts of pharmaceutical compositions to increase oral solubility, thereby improving manufacturability and stability. When a soluble salt dissolves in water, the positively charged component (e.g., tenofovir alafenamide) and the negatively charged component (the fumarate) separate.

262. As long as the pharmacokinetics and safety profile of two different salts of the

same therapeutic moiety (e.g., tenofovir alafenamide) are bioequivalent, the different salts' clinical efficacy is identical. The FDA therefore permits manufacturers to use a streamlined process, under Section 505(b)(2) of the FD&C Act (21 U.S.C. § 355(b)(2)), to get approval for a drug that uses a salt different than that used by the reference drug. The manufacturer usually need not conduct any clinical trials but must merely show that the salt that it proposes to use results in the same safety profile as, and is bioequivalent to, the reference drug. The FDA may also assign an AB-rating to the product, making it automatically substitutable for the reference drug at the pharmacy counter.

263. By making the drug with a different salt than the one used by the brand manufacturer, other manufacturers can get FDA approval while avoiding infringing the brand manufacturer's patents. This is known as "designing around" the patents. Designing around a brand manufacturer's patents on particular salts prevents those manufacturers from using secondary patents to extend their monopolies beyond the expiration of the basic patents that claim the therapeutic moiety itself.

264. Manufacturers could easily design around Gilead's later-expiring Group Two patents (i.e., the patents on the hemifumarate salt), which would allow generic entry in 2023 (when the NCE exclusivity, plus the 30-month stay expire), not 2032.

265. All of Gilead's current TAF-containing products use the hemifumarate salt of tenofovir alafenamide. Gilead originally started clinical development of its TAF product line with the monofumarate salt where the ratio of fumaric acid to tenofovir alafenamide is approximately 1. The monofumarate salt is variously referred to as "GS-7340-02" or "TAF monofumarate." Gilead transitioned to using the hemifumarate salt only during phase II and phase III development of many of its products and for final development.

266. Gilead used the monofumarate salt in some of its own phase II clinical trials and

used those studies to get FDA approval of the hemifumarate-containing final products. Based on Gilead's own data, the FDA concluded that "[the hemifumarate salt] is considered comparable to [the monofumarate salt] based on physical/chemical properties and pharmacokinetic data."[26]

267. In fact, at least three of the initial clinical trials performed by Gilead to evaluate TAF, the GS-120-1101, GS-US-120-0104, and GS-US-292-0101 trials, used the monofumarate rather than hemifumarate salt.[27]

268. Gilead's intentional withholding of the HIV indication impaired the sale of generic TAF-HIV for use in combination with other standalone NRTIs and third agents, in competition with Gilead's TAF-based fixed dose combination. In order to obtain from the FDA an AB-rating to the reference drug, and thus to be automatically substitutable at the pharmacy counter, the applicant must show that the proposed generic drug is bioequivalent to the reference drug and has, among other requirements, the same labeling as the reference drug.

269. Accordingly, a proposed generic TAF-HIV must have the same label as Vemlidy. Gilead intentionally withheld an HIV indication from Vemlidy, so a manufacturer seeking an AB-rating for its standalone TAF product must also omit an HIV indication from its label. The only generic standalone TAF ANDA product, or the only AB-rated ANDA product that will be automatically substitutable for brand Vemlidy at the pharmacy, is one that is not indicated for use in the treatment of HIV.

270. When a generic Vemlidy without an HIV indication becomes available, doctors could, in theory, prescribe it for "off-label" use. However, substantial numbers of doctors will not do so. Federal law (21 C.F.R. § 202.1) makes it unlawful for a pharmaceutical manufacturer to actively encourage doctors to prescribe the product for off-label use. Gilead's intended effect,

[26] FDA, "Pharmacology Review for NDA 207-561," https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207561Orig1s000PharmR.pdf, at 12.
[27] Gilead Sciences, Inc., "Protocol GS-US-320-0108, Amendment 2.1," https://clinicaltrials.gov/ProvidedDocs/36/NCT02836236/Prot_000.pdf, at 31.

then, is to shield Gilead's TAF-based fixed dose combination from competition from combinations of standalone products that include generic standalone TAF.

271. Gilead's conduct also impairs the sale of competing fixed dose combinations made with generic TAF. When generic TAF becomes available, competing manufacturers would be able to formulate fixed dose combination with generic TAF and other antiretrovirals. Gilead's withholding of the HIV indication for standalone TAF thus will substantially complicate, delay, and increase the expense of the regulatory pathway for competing manufacturers.

272. When all of the components of a proposed fixed dose combination have previously received FDA approval for treatment of HIV, an applicant seeking FDA approval need provide only a study showing that the drugs are safe and effective when used together, and some bioavailability data showing that the fixed dose combination produces blood levels for each of the active ingredients adequate to achieve efficacy. Importantly, when all of the components of a proposed fixed dose combination have previously received FDA approval for treatment of HIV, the applicant need not provide to the FDA any new preclinical or safety and efficacy data.

273. In contrast, when all of the components of a proposed fixed dose combination have not previously received FDA approval for treatment of HIV, the applicant must provide new preclinical and safety and efficacy data. The cost and delays attendant upon obtaining and presenting that data to the FDA are substantial. As intended by Gilead, those costs and delays will impair competition to Gilead's TAF-based fixed dose combination.

274. Absent the intended effect of impairing and delaying competition, Gilead's withholding of an HIV indication for TAF made no economic sense for Gilead. Gilead's motive in withholding an HIV indication from TAF was to impair and delay competition. Gilead's forgoing more than $200 million in annual standalone TAF sales is an investment in impairing and delaying competition.

O. Gilead's Anticompetitive Conduct Delays Entry of Generic Viread, Truvada and Atripla.

275. Beginning in 2008, generic drug manufacturer Teva Pharmaceuticals challenged the patents on Gilead's Viread, Truvada, and Atripla. Other generics manufacturers, including Mylan Pharmaceuticals, Lupin Pharmaceuticals, Cipla Ltd., Hetero Drugs Ltd., Amneal Pharmaceuticals, and Aurobindo Pharma, ultimately also challenged the patents on one or more of those products.

276. Viread, Truvada, and Atripla are formulated with TDF and/or FTC. Gilead had shelved TAF, the successor product to TDF, since at least 2004. These challenges to the TDF and FTC patents prompted Gilead to prepare to switch all of its TDF-based franchise to a TAF-based franchise.

277. Gilead's plan to transition the TDF franchise to a TAF franchise would be disrupted, however, if generic versions of Viread, Truvada, or Atripla entered the market before Gilead accomplished the switch to TAF-based products, which were protected by the broader and longer No-Generics Restraints. Gilead prevented the disruption of its anticompetitive schemes by enticing Teva and the other generic manufacturers to delay entry into the market with their generic TDF-based products.

278. Gilead compounded the anticompetitive effects of the No-Generics Restraints by including Most-Favored-Entry ("MFE") and Most-Favored-Entry-Plus ("MFEP") clauses in patent-settlement agreements with Teva and the other generics manufacturers. Gilead used these clauses to entice Teva to delay entry into the market in return for assurance that no other generic manufacturer would enter the market before Teva.

279. An agreement with an MFE clause arises when the brand manufacturer and the "first-filer", the generic manufacturer that filed the first ANDA with a Paragraph IV certification, settle the patent litigation and the generic manufacturer agrees to delay entering the market until a

specified date. The MFE clause provides that if any other generic manufacturer (a "second-filer") succeeds in entering the market before that date, the first-filer may enter at the same time. An MFE can delay generic entry by reducing a second-filer's incentive to try to enter the market before the first-filer.

280. A first-filer that is otherwise entitled to a 180-day period of ANDA Exclusivity can forfeit it. When a second-filer gets a final court decision that the brand manufacturer's patents are invalid or not infringed, the first-filer forfeits its ANDA Exclusivity if it does not enter the market within 75 days of the court decision. 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb). The first-filer would forfeit the statutory exclusivity, for example, if it agreed to delay entry until Year 7 and a second-filer got a final court decision of patent invalidity in Year 5. Having agreed not to begin marketing until Year 7, the first-filer could not enter the market within 75 days of the second-filer's favorable court decision in Year 5. So, the first-filer would forfeit its ANDA Exclusivity. The MFE allows the first-filer to circumvent this statutory provision.

281. Absent an MFE clause, a second-filer could enter in Year 5 and get a substantial period of de facto (non-statutory) exclusivity in the generics sector of the market. The first-filer would be stuck on the sidelines while the second-filer enjoyed de facto exclusivity. Because it is the prospect of obtaining that period of de facto exclusivity that motivates a second-filer to incur the substantial costs and burdens of trying to enter the market before the entry date to which the first-filer agreed, and because an MFE would eliminate that possibility, an MFE would reduce the incentive for second-filers to try to enter the market before the first-filer.

282. Like an MFE, an MFE-Plus (MFEP) dramatically reduces a second-filer's incentive to try to enter the market before the first-filer. An MFEP provides that the brand manufacturer will not grant a license to any second-filer to enter the market until a defined period of time after the first-filer enters. The clause might provide, for example, that the brand

manufacturer will not grant a license to any second-filer to enter the market until 180 days after the first-filer enters.

283. Absent the MFEP, a second-filer could use its challenge to the patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first-filer. And the first- filer's statutory ANDA Exclusivity would not prohibit that earlier entry if, for example, the first-filer forfeited the ANDA Exclusivity by having failed to get tentative FDA approval within 30 months. 21 U.S.C. 355 § (j)(5)(D)(i)(I)(aa)(BB). The second-filer could thereby enjoy a substantial period of de facto exclusivity in the generic sector of the market. An MFEP would eliminate that possibility by ensuring that the second-filer could not successfully negotiate for an earlier licensed entry date.

284. In short, the Hatch-Waxman Amendments leave open at least two pathways for second-filers to enter the market before a first-filer that has agreed to delay entry into the market. The second-filer could win the patent litigation and trigger forfeiture of the first-filer's ANDA Exclusivity when it fails to enter the market within 75 days of the court decision; and the second-filer could negotiate an earlier entry date from the brand manufacturer and enter the market if the first-filer has forfeited statutory exclusivity by having failed to get FDA approval within 30 months. A brand manufacturer could use MFEs and MFEPs to close the two pathways to earlier generic entry that Congress left open.

285. The anticompetitive effects of MFEs and MFEPs may be compounded by increasing the number of generic manufacturers to which the clauses apply. When one second-filer is deciding whether to initiate or continue a patent challenge, four other generic manufacturers might also have already started a patent challenge or be poised to do so. Knowing that the brand manufacturer has already granted an MFE to the first-filer and has offered to grant one to the second-filer himself, the second-filer knows that the brand manufacturer will also likely

grant one to the third, fourth, fifth, and sixth filers.

286. In these circumstances, the second-filer faces the prospect that, even if it expends substantial resources to win the patent case, its "victory" would trigger simultaneous entry into the market by the first-filer, possibly an "authorized generic" marketed by the brand manufacturer, and four other generics. As shown in detail below, entry by that number of manufacturers would quickly compete prices down to near marginal cost.

287. The use of MFEs and MFEPs may therefore mean that no other generic manufacturer can profitably invest in using its patent challenge to try to get earlier entry than the first-filer.

288. Gilead used MFEPs and MFEs to delay the onset of generic competition to Viread, Truvada, and Atripla. The MFE agreements set a date for initial generic entry and provided that the first-filer, Teva, could enter sooner should a second-filer gain entry into the market by, for example, proving the Gilead patents invalid. The MFEP clauses compounded the anticompetitive effects of these provisions by promising that Gilead would not authorize further generic entry for a defined period after the initial entry. These anticompetitive clauses, together with the unlawful No-Generics Restraints that Gilead had already used, worked. All generic manufacturers agreed to stay out of the market for the period of time that Gilead granted to Teva in the MFEP, and Teva agreed to delay entry into the market.

289. On September 26, 2008, Teva filed the first ANDA seeking FDA approval to sell generic Truvada. Teva's ANDA, which was assigned ANDA No. 90894, contained a Paragraph IV certification as to Gilead's patents 6,642,245 and 6,703,396 that claim the FTC composition (the "FTC Enantiomer Patents"), which were set to expire on May 4, 2021 and September 9, 2021, respectively. Teva asserted that the patents were invalid, unenforceable, or not infringed by its proposed generic version of Truvada.

290. On the same day, Teva also filed the first ANDA seeking FDA approval to sell generic Atripla. Teva's ANDA, which was assigned ANDA No. 91215, contained a Paragraph IV certification as to the FTC Enantiomer Patents and to BMS's patents covering EFV. Teva also provided a Paragraph IV certification as to Gilead's basic patents claiming TDF and certain methods of using it, U.S. Patents 5,922,695; 5,935,946; 5,977,089; and 6,043,230 (the "TDF Patents"). Teva asserted that the TDF patents were invalid, unenforceable, or not infringed.

291. On or about November 3, 2008, Teva notified Gilead that Teva had filed the ANDAs and explained in detail why the patents were invalid and not infringed by Teva's ANDA products.

292. On December 12, 2008, Gilead filed suit in the United States District Court for the Southern District of New York (Case No. 08-cv-10838), alleging that Teva's generic Truvada would infringe the FTC Enantiomer Patents. On September 25, 2009, Gilead filed an amended complaint, adding allegations that Teva's generic Atripla would infringe the FTC Enantiomer Patents. Gilead filed the patent infringement lawsuit without regard to its merits. Gilead knew that there was a substantial risk that it would lose the patent litigation.

293. On July 1, 2009, Teva filed the first ANDA seeking FDA approval to sell generic Viread. Teva's ANDA, which was assigned ANDA No. 91692, contained a Paragraph IV certification as to the TDF Patents, claiming that they were invalid, unenforceable, or not infringed. On or about January 25, 2010, Teva notified Gilead that Teva had filed ANDA No. 91692, detailing why the TDF Patents were invalid and not infringed by Teva's ANDA product.

294. On March 5, 2010, Gilead filed suit in the United States District Court for the Southern District of New York (Case No. 10-cv-01796) alleging that Teva's generic Viread would infringe the TDF Patents. Gilead filed the patent infringement lawsuit against Teva without regard to the lawsuit's merits. Gilead knew that there was a substantial risk that it would lose the

patent litigation.

295. Thereafter, the litigation of the TDF patents, which affected Teva's applications for Viread, Truvada, and Atripla (all of which contain TDF) was conducted in Southern District of New York (Case No. 10-cv-01796). The litigation of the FTC Enantiomer Patents, which affected Teva's applications for Truvada and Atripla (both of which contain FTC), was conducted in Southern District of New York (Case No. 08-cv-10838).

296. Subsequent events set the stage for Gilead to use MFEPs and MFEs to elicit delayed entry from Teva and all other generic manufacturers that sought to market generic Viread, Truvada, and Atripla.

297. From March 2010 to February 2013 (when Gilead enticed Teva into a settlement on Viread), six more generic-drug manufacturers, Lupin, Cipla, Hetero, Aurobindo, Strides Pharma, and Macleods Pharmaceuticals, filed ANDAs seeking FDA approval to sell generic Viread. The first two of those six manufacturers included Paragraph IV certifications with respect to the TDF Patents. Gilead and Teva knew and understood that the other four of those six intended to enter the market as soon as possible and would amend their ANDAs to include Paragraph IV certifications (as is common in the industry) if it appeared that they had an opportunity for a period of de facto exclusivity.

298. These competitors posed a significant threat to Teva. The FDCA's forfeiture provisions created the prospect that, if Teva agreed to a long delay in entry, without the protection of an MFEP and MFE, a second-filer would: (a) obtain a judgment of invalidity or noninfringement and enter the market years before Teva; or (b) would use the leverage of its patent challenge to negotiate a better licensed-entry date from Gilead. Without those clauses, Teva faced a substantial risk that it would not be able to enter the market while second-filers entered the market years in advance and reaped the corresponding gains of being the first ANDA

entrants.

299. Gilead enticed Teva to enter into the settlement for Viread in part by using MFE and MFEP clauses to forestall generic competition to Teva after it entered the market. This reduction in generic competition was enormously valuable to Teva. For every week that Teva was on the market as the only generic manufacturer of a standalone product such as Viread, it could expect to sell all of the generic units at about 90% of the price of branded Viread. Entry of other generics, however, would significantly cut Teva's unit sales and the profits per sale. A third generic version would cut Teva's unit share to a third and permit a price of only 44% of the branded price; entry of a seventh version would cut Teva's unit share to one-seventh and permit a price of only 23% of the brand price.

300. In 2017 (the year that Teva eventually entered the market) Viread had United States sales of $591 million, or about $11 million per week. Generics collectively (however many there were) could expect to take 80% of Viread's unit sales. As the sole generic on the market, Teva could expect to make $7.9 million for every week of sales; with seven generics on the market, Teva could expect to make only $289,000 for every week of sales.

301. Gilead's efforts to forestall generic competition increased Teva's sales by $7.6 million for every week in which it was the only generic Viread seller. Moreover, Teva's competitive advantage would not be limited just to the period when no other manufacturer was selling the product. With a date-certain, single-entrant launch date, Teva could ramp up its production and negotiate contracts with its customers to effectively stuff the distribution channel with many more weeks of product before the second-filers entered the market, and to lock in high prices with long-term sales contracts.

302. To delay entry of generic Viread, Gilead gave Teva an MFEP and put MFE clauses in all of its settlement agreements with the generic manufacturers. The MFE clauses caused Teva

to agree to delay entry and caused all of the second-filers to agree to delay entry until at least six weeks after Teva entered.

303. The first MFE appeared on November 27, 2012 in an interim agreement between Gilead and Teva, in which Teva agreed that it would not enter the market with Viread or Truvada while the TDF patent litigation was pending, until the earlier of (i) various events in the patent litigation (e.g., a finding of invalidity), or (ii) a second-filer entered the market. Gilead and Teva put this MFE in the public record, so all of the second-filers knew that any final agreement between Gilead and Teva was also very likely to include an MFE.

304. In February 2013, Gilead and Teva agreed in principle to settle their litigation over the TDF Patents, and they finalized the agreement in April 2013. Under the agreement, Teva agreed to delay marketing its generic Viread and any TDF-containing product until December 15, 2017.

305. The MFE and MFEP allowed Gilead to set a late entry date of just six weeks before the end of the patent term. The MFE provided that, if any second-filer entered the market before December 15, 2017, Teva's entry date would be moved up accordingly. The MFEP provided that Gilead would not grant any other manufacturer a license to enter the market with generic Viread until at least six weeks after Teva's agreed entry date.

306. The MFE and MFEP allowed Gilead to obtain a later entry date than Teva otherwise would have agreed to. Without the clauses, Teva faced the prospect of simultaneous entry by as many as six other generic manufacturers. With the clauses, Teva was nearly guaranteed a period of time as the only generic on the market, and was absolutely guaranteed that no other generic manufacturer would enter before it.

307. When agreeing to the delayed December 15, 2017 entry date, Teva knew that: (1) Gilead was willing to include the anticompetitive MFEs in settlement agreements with second-

filers; (2) it was in Gilead's financial interest to include such clauses in agreements with all second-filers; (3) the second-filers knew that the Gilead/Teva agreement included an MFE; (4) given the MFE and MFEP, it was not in any second-filer's interest to incur the costs of patent litigation to try to enter the market before Teva; and (5) the MFEs' deterrent effect would grow with every additional one that Gilead included in another settlement.

308. Upon information and belief, Gilead advised the second-filers of the existence of the MFE and MFEP in the Gilead/Teva agreement.

309. Teva concluded that the MFE and MFEP would protect it from competition from any other generic manufacturer until the end of the TDF Patent terms on January 26, 2018, six weeks after Teva entered.

310. By the time that Gilead and Teva finalized their agreement in April 2013, Gilead had filed patent infringement lawsuits against Lupin and Cipla, both of which had provided Paragraph IV certifications with respect to the TDF Patents. On May 28, 2014 and July 29, 2014, Gilead settled those patent litigations with Lupin and Cipla, respectively. Both generic manufacturers agreed under their respective settlements not to launch generic Viread until six weeks after Teva. Gilead included an MFE clause in both of those settlement agreements.

311. The MFE and MFEP in the Teva agreement, and the MFEs in the Lupin and Cipla agreements, caused the other ANDA filers Hetero, Aurobindo, Strides, and Macleods to not amend their ANDAs to include Paragraph IV certifications. Absent Gilead's anticompetitive conduct, at least Hetero and Aurobindo would have done so, as those manufacturers made Paragraph IV certifications with respect to Truvada.

312. On January 26, 2018, six weeks to the day after Teva entered the market, five additional generic manufacturers (Cipla, Hetero, Aurobindo, Strides, and Macleods) received final FDA approval, and four of them immediately began marketing their generic Viread.

313. During the six weeks that Teva had the only generic Viread on the market, Teva flooded the market with product, sold at least 14 weeks' supply of product, and locked in high prices through long-term sales contracts. Teva made at least $106 million more than it would have absent the MFEP and MFEs. Absent the MFEP and MFEs, Teva and the second-filers would have entered the market much sooner than they did, on dates to be determined by the jury. The delay in generic entry protected more than $2 billion in Gilead's Viread branded sales.

314. Gilead's delaying the entry of generic Viread also had the effect of delaying the entry of Gilead's TAF-based line of products. Gilead withheld those products from the market until the entry of generic TDF was imminent. The delay in that generic entry caused Gilead to delay the introduction of its TAF-based products.

315. Having successfully delayed generic entry for Viread, Gilead then also used MFE/MFEP clauses to delay generic entry for Truvada and Atripla.

316. Following various amendments and pretrial proceedings in Gilead's patent litigation against Teva, only the FTC Enantiomer Patents, as they related to both Truvada and Atripla, were left for trial. The trial, which began on October 8, 2013 and concluded on October 28, 2013, focused on Teva's contention that the patents were invalid for obviousness-type double patenting because the (-)-enantiomer "species" patents were anticipated by earlier expiring "genus" patents, which claimed all enantiomeric forms of the FTC compound, and that the claimed (-)-enantiomer was disclosed as part of the genus patents' claims. The parties settled the case in February 2014 while they were awaiting the trial court's decision.

317. The '396 patent (the later of the two FTC Enantiomer Patents) does not expire (with pediatric exclusivity) until September 9, 2021. As with Viread, a number of second-filers had lined up behind Teva; by February 2014, Gilead had filed patent lawsuits on the FTC Enantiomer Patents against Lupin, Mylan, Aurobindo, Hetero, and Amneal, all of which had

provided Paragraph IV certifications with respect to Truvada. And Gilead had filed a patent infringement lawsuit against other generic manufacturers, including Lupin, which provided Paragraph IV certifications with respect to Atripla. (BMS's EFV patents expired before Gilead's FTC Enantiomer Patents, so BMS sued and settled with Teva, knowing that the generic entry date would be determined by resolution of Gilead's lawsuit against Teva.)

318. With respect to Teva and the second-filers, Teva's getting an MFE and MFEP would dissuade the second-filers from continuing to litigate and would provide Teva a period of exclusivity. Teva had forfeited its 180-day ANDA Exclusivity with respect to Truvada, and may have forfeited it with respect to Atripla, by having failed to obtain tentative FDA approval within 30 months of submitting its application. 21 U.S.C. 355 § (j)(5)(D)(i)(I)(aa)(BB). Under the February 2014 settlement agreement, Teva will not be able to launch generic Truvada and generic Atripla until September 30, 2020. Gilead was able to set that late entry date, just one year before the end of the patent term, by giving Teva an MFE and MFEP. The MFE provided that, if any second-filer entered the market before Teva's agreed entry date, Teva's permitted entry would be moved up accordingly. The MFEP provided that Gilead would not grant a license to any other manufacturer to enter the market with generic Truvada or generic Atripla until at least six months after Teva's agreed entry date.

319. Upon information and belief, Gilead advised the second-filers of the existence of the MFE and MFEP in the Gilead/Teva agreement.

320. Gilead succeeded in delaying entry of generic Truvada and Atripla just as it did with respect to Viread. Gilead settled the FTC Enantiomer litigations with Lupin in September 2014; with Mylan in October 2015; with Aurobindo in September 2016; with Hetero in August 2016; and with Amneal in April 2017. Gilead included an MFE in each of those settlement agreements, and all of the manufacturers agreed to delay entering the market until six months

after Teva's entry.

321. The MFE and MFEP had very substantial value to Teva. In 2014, combined United States sales for Atripla and Truvada were approximately $4 billion. Six months of exclusive sales of those generic products was worth more than $1.5 billion to Teva. Absent the MFEP and MFEs, Teva and the second-filers would have entered the market much sooner than they did. The delay in generic entry protected more than $25 billion in Gilead's Truvada and Gilead/BMS's Atripla branded sales.

VII. DEFENDANTS' ACTIONS IMPACT INTERSTATE TRADE AND COMMERCE

322. During the relevant time period, the Defendants manufactured, sold, and shipped cART regimen drugs across state lines in an uninterrupted flow of interstate commerce.

323. The business activities of Defendant that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.

324. Defendant's conduct, including the marketing and sale of cART regimen drugs, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States. During the relevant time period, the Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce.

325. The unlawful contract combination and restraint of trade and conspiracy to monopolize the market for cART regimen drugs as alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff and Class Members of the benefits of free and open competition in the purchase of cART regimen drugs within the United States.

326. The effects of Defendants' anticompetitive contract in restraint of trade and

conspiracy to monopolize were to inflate, fix, raise, maintain, or artificially stabilize prices of cART regimen drugs, and its actual inflating, fixing, raising, maintaining, or artificially stabilizing cART regimen drugs prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

VIII. MARKET POWER

327. The relevant geographic market is the United States and its territories and possessions.

328. At all relevant times, Gilead had market power over each of Viread, Emtriva, Truvada, Vemlidy, Descovy, Tybost, and their generic equivalents; Gilead and BMS had market power over each of Atripla and Evotaz and their generic equivalents; Gilead and Japan Tobacco had market power over each of Stribild and Genvoya and their generic equivalents; Gilead and Janssen had market power over each of Complera, Odefsey, Prezcobix, and Symtuza and their generic equivalents; BMS had market power over Reyataz and its generic equivalents; and Janssen had market power over each of Edurant and Prezitsa and their generic equivalents. The Defendants had the power to maintain the price of those brand drugs at supracompetitive levels without losing sufficient sales to other products, except for AB-rated generic versions of those brand drugs, to make the supracompetitive prices unprofitable.

329. A small but significant, non-transitory increase in the brand drugs' price above the competitive level did not cause a loss of sales sufficient to make the price increase unprofitable. At competitive prices, none of the brand drugs exhibits significant, positive cross-elasticity of demand with respect to price with any product other than AB-rated generic versions of the brand drugs.

330. Each of the brand drugs is differentiated from all drug products other than AB-rated generic versions. Due to, among other reasons, its use and varying ability to treat the conditions for which it is prescribed, and its side-effects profile, each of the brand drugs is differentiated from all drug products other than AB-rated generic versions.

331. Additionally, once the physician and patient find that one of these drugs is well tolerated, at competitive prices based on variations of price of 10% or less, the doctor and patient are very unlikely to switch to a different HIV drug.

332. The pharmaceutical marketplace is characterized by a "disconnect" between product selection and the payment obligation. State laws prohibit pharmacists from dispensing many pharmaceutical products, including all of those at issue in this complaint, to patients without a prescription. The prohibition on dispensing certain products without a prescription creates this disconnect. The patient's doctor chooses which product the patient will buy while patient (and in most cases his or her insurer) has the obligation to pay for it.

333. Brand manufacturers, including Gilead, BMS, and Janssen, exploit this price disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of costs, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

334. The relative unimportance of price in the pharmaceutical marketplace reduces the price elasticity of demand or the extent to which unit sales go down when price goes up. This reduced price-elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The

ability to profitably raise prices substantially above marginal costs is market power. Thus, brand manufacturers gain and maintain market power with respect to many branded prescription pharmaceuticals, including the cART drugs at issue here.

335. The existence of other branded HIV drugs has not constrained the price of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, or Symtuza to the competitive level.

336. Each Defendant needed to control only each of its brand drugs and its AB-rated generic equivalents, and no other products, in order to maintain the price of the brand drug profitably at supracompetitive prices. Only the market entry of a competing, AB-rated version of the brand drug would render the brand manufacturer unable to profitably maintain its brand-drug prices at supracompetitive levels.

337. Defendants sold these brand drugs at prices well in excess of marginal costs, substantially in excess of the competitive price, and enjoyed unusually high profit margins.

338. Defendants had the ability to control the prices of these drugs and exclude relevant competitors. Among other things: (a) generic versions of each drug would have entered the market at substantial discounts to the brands but for the Defendants' anticompetitive conduct; (b) the gross margin on each drug was at all times at least 70%; and (c) Defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

339. At all relevant times, Gilead's gross profit margin on its cART drugs, collectively, has exceeded 75% and has reached as high as 91%. These margins are approximately 15 times those that indicate substantial market power.

340. To the extent that Plaintiff is required to prove market power through circumstantial evidence by first defining a relevant product market, at least two types of markets

are relevant here: (a) the market for each of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza and its AB-rated generic equivalent; and (b) the cART Market.

341. As discussed, the purpose and effect of Defendants' No-Generics Restraints was to impair competition in multiple ways. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in multiple markets.

342. One purpose and effect of Defendants' No-Generics Restraints was to impair competition from generic versions of each of Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Atripla, Complera, Odefsey, Stribild, Genvoya, Reyataz, Evotaz, Prezista, Prezcobix, Edurant, and Symtuza. A relevant market for evaluating that conduct is the market for each of those products and its AB-rated generic equivalent. As demonstrated by the indicia noted above:

a. from October 2001 to December 17, 2017, Gilead had market power in the market for Viread and its AB-rated generic equivalents, and during that time had 100% of the shares of that market;

b. from November 10, 2016 to the present, Gilead has had market power in the market for Vemlidy and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

c. from April 4, 2016 to the present, Gilead has had market power in the market for Descovy and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

d. from July 7, 2003 to the present, Gilead has had market power in the market for Emtriva and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

e. from September 2014 to the present, Gilead has had market power in the market for Tybost and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

f. from August 2, 2004 to the present, Gilead has had market power in the market for Truvada and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

g. from July 12, 2006 to the present, Gilead and BMS have had market power in the market for Atripla and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

h. from August 10, 2011 to the present, Gilead and Janssen have had market power in the market for Complera and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

i. from March 1, 2016 to the present, Gilead and Janssen have had market power in the market for Odefsey and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

j. from August 27, 2012 to the present, Gilead and Japan Tobacco have had market power in the market for Stribild and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

k. from November 5, 2015 to the present, Gilead and Japan Tobacco have had market power in the market for Genvoya and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

l. from June 20, 2003 to December 2017, BMS had market power in the market for Reyataz and its AB-rated generic equivalents, and during that time had 100% of the shares of that market;

m. from April 4, 2014 to the present, Gilead and BMS have had market power in the market for Evotaz and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

n. from June 23, 2006 to the present, Janssen has had market power in the market for Prezista and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market;

o. from March 31, 2014 to the present, Gilead and Janssen have had market power in the market for Prezcobix and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market;

p. from May 20, 2011 to the present, Janssen has had market power in the market for Edurant and its AB-rated generic equivalents, and during that time has had 100% of the shares of that market; and

q. from September 22, 2017 to the present, Gilead and Janssen have had market power in the market for Symtuza and its AB-rated generic equivalents, and during that time have had 100% of the shares of that market.

343. Defendants also had market power during relevant times in broader markets comprising the branded drug and comparable versions of it. For example, Gilead and Janssen

have market power in the market for Complera and comparable versions made of genericTDF/3TC/RPV and have market power in the market for Symtuza and comparable versions made of genericTAF/genericFTC (or 3TC)/RTV/DRV.

344. Another purpose and effect of Defendants' No-Generics Restraints was to impair competition among drugs used in the cART regimen. To the extent that Plaintiff is required to define a relevant market in which that purpose and effect is evaluated, it is properly evaluated in the market for such drugs, i.e., the cART Market, and narrower markets therein.

345. As noted in detail above, a cART regimen is a course of treatment distinct from other drugs and regimens that might be used to treat HIV. Effective cART reduces the concentration of HIV virus in treated patients to undetectable levels. Patients on effective cART can live healthy lives and have a normal life expectancy. And a patient living with HIV who maintains an undetectable viral load durably cannot transmit the virus to others. Under the guidelines of the HHS, WHO, and all major HIV-treatment organizations, every HIV treatment regimen, with inconsequential exceptions, is a cART regimen.

346. Doctors and patients using a cART regimen almost always choose two NRTIs. For very substantial medical reasons, doctors and patients overwhelmingly choose Tenofovir as one of those two NRTIs. Among other reasons, as noted above, all other NRTIs are triple phosphorylated by host kinases to be activated, and Tenofovir, by contrast, needs to be phosphorylated only twice by host kinases, into its active form, tenofovir diphosphate (TFV-DP).

347. The following table identifies all NRTIs that have been available in the United States since 1987.

Table 5. Available NRTI's

DRUG NAME AND MANUFACTURER	DATE OF APPROVAL
Zidovudine (Retrovir) AZT • Manufactured by ViiV (Burroughs Wellcome) • Used less commonly due to side effects	3/19/87
Didanosine (Videx) ddI • Manufactured by BMS • Not used commonly due to side effects/inferiority	10/9/91
Zalcitabine (Hivid) ddC • Manufactured by Roche • Discontinued in 2001 due to toxicity	6/22/92
Stavudine (Zerit) d4T • Manufactured by BMS • Usage strongly discouraged by WHO	6/24/94
Lamuvidine (Epivir) 3TC • Manufactured by ViiV (Glaxo) • Interchangeable with FTC if used as HIV treatment	11/17/95
Abacavir (Ziagen) ABC • Manufactured by ViiV (Glaxo) • Cannot be used in patients in HLA-B*5701 + pts	12/18/98
Tenofovir Disoproxil Fumarate TDF • Manufactured by Gilead	10/26/01
Emtricitabine FTC • Manufactured by Gilead • Interchangeable with FTC if used as HIV treatment	7/2/03
Tenofovir Alafenamide Fumarate TAF • Manufactured by Gilead	11/5/15

Table 5. Available NRTI's	
DRUG NAME AND MANUFACTURER	**DATE OF APPROVAL**
• First approved as a single tablet regimen (Genvoya)	

348. Zidovudine is not a significant competitor to Tenofovir because of Zidovudine's impact on the bone marrow, gastrointestinal side effects, mitochondrial toxicity, and inferior antiviral potency when used with some third agents. In 2018, Zidovudine's United States sales, including when coformulated with 3TC, were less than $60 million.

349. Didanosine is not a significant competitor to Tenofovir because of Didanosine's tendency to cause peripheral neuropathy and pancreatitis, the requirement that it be taken on an empty stomach, and its inferior antiviral potency when used with some third agents.

350. In 2001, all United States sales of Zalcitabine were halted due to toxicity side effects.

351. The WHO strongly discourages doctors from prescribing Stavudine (d4T) due to lipodystrophy, peripheral neuropathy, and other severe side effects. Stauvudine's United States sales were less than $3 million in 2018.

352. The principal NRTIs for use in a cART regimen are Tenofovir, abacavir, FTC, and 3TC. Tenofovir-containing cART regimens usually also contain either FTC or 3TC, because a common mutation associated with resistance to FTC and 3TC increases the susceptibility of the virus to Tenofovir. Taking Tenofovir together with either FTC or 3TC makes it more difficult for the virus to become resistant to the cART regimen. Consequently, 3TC is a competitor to FTC, but is a complement to, not a substitute for, the use of Tenofovir or abacavir in a cART regimen.

353. For many doctors and patients, Abacavir is not a realistic substitute for Tenofovir in a cART regimen. Gilead noted at a 2016 investors conference, for example, that "[a]bacavir is a molecule that is the most difficult of the … [NRTIs] to administer and has both short-term and long-term problems associated with it."

354. Specifically, a substantial number of patients are HLA-B*5701 positive, meaning that they are at an increased risk of a hypersensitivity reaction to abacavir, resulting in a severe systemic illness that can result in death. Consequently, doctors will not prescribe abacavir to patients without first requiring that they get either a blood test or cheek-swab test to screen them for HLA-B*5701. This dissuades many doctors from prescribing abacavir and prevents them altogether from starting patients on abacavir without the required screening. This is a significant barrier to treatment. Most modern treatments programs are based on the "test and treat" paradigm in which doctors encourage patients to begin HIV treatment on the day they are diagnosed, so they will not subsequently be lost to follow up.

355. At all relevant times, Gilead's dominance with respect to Tenofovir allowed it to exercise market power in the cART Market. From October 26, 2001 through December 15, 2017, Gilead had 100% of the unit shares of all sales in the United States of Tenofovir. Even after the entry of generic TDF in December 2017, Gilead has maintained at least 85% of all unit sales of Tenofovir in the United States.

356. At all relevant times, Gilead has maintained at least 70% of all unit sales of NRTIs in the United States.

357. At all relevant times, Gilead's unit share of the cART Market has ranged from not less than 70% to as much as 93%. Gilead has repeatedly acknowledged, indeed touted, its monopoly share in the cART Market.

358. As early as 2007, Truvada and Atripla alone accounted for 82% of new starts in treatment-naïve (those new to therapy) HIV patients. And as recently as 2018, a Gilead presentation to investors highlighted the fact that 81% of treatment-naïve HIV patients regularly took at least one Gilead product.

359. A purpose and effect of Gilead's degrading (and supra-profit-maximizing pricing) of Stribild, degrading of standalone TAF, and regulatory gaming with respect to standalone TAF was to impair competition among drugs used in the cART regimen. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in the cART Market and narrower markets therein.

360. Another purpose and effect of Gilead's degrading of standalone TAF and regulatory gaming with respect to standalone TAF was to impair competition from generic versions of standalone TAF and generic versions of TAF-containing fixed dose combinations. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in the markets for each of those products and their AB-rated equivalents.

361. The purpose and effect of Gilead's delaying the entry of generic versions of Viread, Truvada, and Atripla was to impair competition in multiple ways. To the extent that Plaintiff is required to define a relevant market in which that conduct is evaluated, it is properly evaluated in: (1) the market for each of those products and its AB-rated generic equivalents; and (2) the cART Market and narrower markets therein.

362. At all relevant times, the Defendants were protected by high barriers to entry with respect to the above-defined relevant markets due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and

money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or may be covered by patents or other forms of intellectual property. Defendants' unlawful No-Generics Restraints and other unlawful conduct further restricted entry. Thus, existing and potential market entrants lack the ability to enter the market and/or expand output quickly in the short run in response to Defendants' higher prices or reductions in output.

IX. EFFECTS OF DEFENDANTS' VIOLATIONS OF THE ANTITRUST LAWS

A. Plaintiff and Class Members Incurred Money Damages.

363. Defendants' contract in restraint of trade and conspiracy to monopolize had the following anticompetitive effects in the market for cART regimen drugs:

(a) Competition in the market for cART regimen drugs has been reduced or eliminated;

(b) Prices for cART regimen drugs have maintained at supracompetitive levels; and

(c) U.S. purchasers have been deprived of the benefit of price competition in the market for cART regimen drugs.

364. As described herein, During the Class Period, Plaintiff and Class Members directly purchased cART regimen drugs from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for cART regimen drugs than they would have and thus suffered substantial damages. Plaintiff and Class Members have sustained substantial losses and damage to their business and property in the form of overcharges. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

365. Given Gilead's dominance of the cART Market, the monopoly prices on its products had the predictable effect of causing its competitors to raise prices on their cART drugs. For example, from July 2011 to October 2017, Gilead raised its price on Complera by 45%. ViiV Healthcare raised the price of Selzentry (a CCR5 coreceptor antagonist) by 47%. Likewise, until it encountered generic competition Boehringer Ingelheim's NNRTI, Viramune XR, similarly

followed Gilead's price increases in lockstep. Defendants' unlawful monopolization of the cART Market caused the price of every drug in the market to be higher than it would have been absent that conduct.

366. As a consequence, Plaintiff and the Class Members have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

367. The unlawful conduct of Defendants' unlawful conduct deprived Plaintiff and the Class Members of the benefits of competition that the antitrust laws were designed to ensure.

368. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class Members continue to pay supracompetitive prices for cART regimen drugs.

B. Plaintiff and Class Members Are Entitled to Injunctive Relief.

369. Unless enjoined by this Court, Defendants' unlawful conduct will have additional and intensified anticompetitive effects once generic versions of any of FTC, TAF, COBI, or DRV become available. Absent the No-Generics Restraints, a competitor in Japan Tobacco's position would produce and market a substitutable version of Stribild when generic FTC and generic COBI become available; and such a competitor in Janssen's position would make a substitutable version of Complera when generic FTC becomes available.

370. Absent the No-Generics Restraints, when generic TAF becomes available, a competitor in Japan Tobacco's position would produce and market a comparable version of Genvoya, comprising generic TAF, generic 3TC, generic RTV, and EVG. Such a competitor would also make a substitutable version of Genvoya once generic versions of TAF, FTC, and COBI become available.

371. Moreover, a competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them. The competitor would have

sought FDA approval for a substitutable version of Genvoya as early as November 5, 2019 (when the applicable NCE exclusivity expired), and if Gilead had timely sued, the 30-month stay would have expired on May 5, 2023, allowing the competitor to begin marketing the substitutable fixed dose combination. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until the pact expires on April 24, 2030.

372. Absent the No-Generics Restraints, when generic TAF becomes available, a competitor in Janssen's position would produce and market a comparable version of Odefsey, comprising generic TAF, generic 3TC, and RPV. Such a competitor would also make a substitutable version of Odefsey once generic versions of TAF and FTC become available.

373. Moreover, the competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them. Assuming that Janssen was subject to NCE exclusivity that protected Odefsey and did not obtain a waiver of it, a competitor in Janssen's position would have sought FDA approval for a substitutable version of Odefsey as early as November 5, 2019, and, after waiting out the 30-month stay, begun marketing the substitutable fixed dose combination on May 5, 2023. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until March 2026.

374. Absent the No-Generics Restraints, when generic TAF becomes available, a competitor in Janssen's position would also produce and market a comparable version of Symtuza, comprising generic TAF, generic FTC (or generic 3TC), generic RTV, and DRV. Such a competitor would also make a substitutable version of Symtuza once generic versions of TAF, FTC, and COBI become available. Moreover, that competitor would have accelerated the availability of generic versions of those compositions by challenging Gilead's patents on them.

375. Assuming that Janssen were subject to NCE exclusivity that protected Symtuza and did not obtain a waiver of it, a competitor in Janssen's position would have sought FDA

approval for a substitutable version of Symtuza as early as November 5, 2019, and, after waiting out the 30-month stay, begun marketing the substitutable fixed dose combination in May 2023. Unless enjoined by this Court, however, the unlawful No-Generics Restraint will prevent that competition until 2026.

376. Absent the No-Generics Restraint, a competitor in Gilead's position would have produced and marketed a substitutable version of Symtuza as soon as possible. Such a competitor would have submitted an application for a product containing TAF, FTC, COBI, and generic DRV as early as FDA approval of Symtuza's NDA (Gilead controlled the NCE exclusivity for Symtuza). After waiting out the 30-month stay, that competitor would have begun marketing the substitutable fixed dose combination on January 17, 2021. By that date, the only non-expired Orange Book patents owned by Janssen will be those covering certain pseudopolymorphic forms of DRV, which expire on February 16, 2024 and December 26, 2026 (assuming no pediatric exclusivity is later awarded). Those patents are invalid and can easily be designed around. But the unlawful No-Generics Restraint resulted in Gilead's agreeing not to compete until at least July 17, 2028. Unless enjoined by this Court, the unlawful pact will continue to deprive drug purchasers of such a competing fixed dose combination.

377. Gilead's unlawful degrading of Stribild and standalone TAF, and its regulatory gaming with respect to TAF, also significantly distorted the market, are causing ongoing harm, and threaten future harm. That unlawful conduct requires this Court's intervention. Without affirmative relief from the Court to help restore competitive conditions, that unlawful conduct will continue to deprive drug purchasers of the benefits of competition to which they are entitled. For example, Gilead's regulatory gaming with respect to TAF, unless enjoined by this Court, will significantly delay and impair the competition from generic standalone TAF and from generic-TAF-based fixed dose combination that should flourish in or about May 2023.

378. Gilead's anticompetitively delaying generic versions of Viread, Truvada, and Atripla is similarly causing ongoing harm that requires this Court's intervention. Unless enjoined by this Court, Gilead's anticompetitive conduct with respect to Truvada will cause Teva to delay entry until September 30, 2020 and cause all other generic manufacturers that would enter the market following Teva to delay entry until March 30, 2021. That delay will cost purchasers of Truvada more than $1 billion in addition to the billions on purchases of Truvada that Defendants' other unlawful conduct has already caused. Significantly, Truvada is the only FDA-approved drug indicated for preventing HIV in patients who are HIV-negative, also known as pre-exposure prophylaxis (PrEP). Thus, Gilead's delay of generic Truvada will preclude access to PrEP and will result in preventable HIV infections.

379. Unless enjoined by this Court, Gilead's anticompetitive conduct will also cause Teva to delay entry with generic Atripla until September 30, 2020 and cause all other generic manufacturers that would enter the market following Teva to delay entry until March 30, 2021. That delay will cost purchasers of Atripla more than $1 billion in addition to the billions that Defendants' other unlawful conduct has already caused on purchases of Atripla.

380. Defendants' conduct is also continuing to unlawfully delay the entry of generic TAF. Defendants' conduct resulted in Gilead's delaying the introduction of TAF and TAF-based fixed dose combination from 2006 to 2015. Absent that delay, the NCE exclusivity for TAF would have expired by 2011, and 30-month stays on generic entry would have expired by 2013. With Gilead's delaying the introduction of TAF to 2015, no generic has yet been able to challenge the relevant TAF patents, because the NCE exclusivity does not expire until November 5, 2020.

381. In order to help restore competitive conditions, this Court should enjoin Gilead from enforcing any of its TAF-related NCE exclusivities and 30-month stays. Other affirmative relief, including compulsory licenses to the affected products, will also be required.

X. CLASS ACTION ALLEGATIONS

382. Pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), Plaintiff brings this action on behalf of a Direct Purchaser Class defined as follows:

> All persons in the United States and its territories that directly purchased cART regimen drugs from May 14, 2015 until the anticompetitive effects of the defendants' conduct cease.

383. Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

384. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that the Class is numerous, geographically dispersed throughout the United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by Defendants.

385. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

386. Plaintiff will fairly and adequately protect and represent the interests of the Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

387. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.

388. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class; therefore, determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

389. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether the No-Generics Restraints entered into between Gilead and each of BMS, Janssen, and Japan Tobacco were an unlawful restraint of trade;

(b) Whether Gilead unlawfully degraded Stribild;

(c) Whether Gilead unlawfully degraded standalone TAF;

(d) Whether Gilead unlawfully created artificial price differences between Stribild and Genvoya;

(e) Whether Gilead unlawfully impaired competition through its regulatory gaming with respect to standalone TAF;

(f) Whether Gilead anticompetitively delayed the entry of generic versions of Viread, Truvada, and Atripla;

(g) Whether Gilead and its coconspirators unlawfully obtained or maintained a monopoly in the cART Market;

(h) Whether the law requires definition of a relevant market when direct proof of market power is available, and if so, the definition of the relevant market;

(i) Whether Defendants' conduct as alleged herein substantially affected interstate and intrastate commerce;

(j) Whether, and if so, to what extent, Defendants' conduct caused antitrust injury (i.e., overcharges) to Plaintiff and Class Members;

(k) The quantum of overcharges paid by the class in the aggregate.

390. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

391. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

XI. CLAIMS FOR RELIEF

COUNT 1 – CONSPIRACY TO MONOPOLIZE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 AGAINST ALL DEFENDANTS

392. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

393. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possesses the power to control prices in, prevent prices from falling in, and exclude competitors from the cART Market.

394. That market power is coupled with strong regulatory and contractual barriers to entry into the cART Market.

395. Through an overarching anticompetitive scheme, Gilead willfully maintained its monopoly power in the cART Market using restrictive or exclusionary conduct, rather than by

means of greater business acumen, and caused injuries to the business and property of Plaintiff and the Class Members.

396. Gilead's conscious objective was to further its dominance in the cART Market by and through the overarching anticompetitive scheme.

397. Each of Janssen, Japan Tobacco, and BMS consciously committed to the overarching anticompetitive scheme.

398. As stated more fully above, Gilead and its coconspirator Defendants knowingly, willfully, and wrongfully maintained Gilead's monopoly power and harmed competition by:

a. Entering into and abiding by the illegal No-Generics Restraints;

b. Degrading Stribild and artificially raising its price in order to drive patients to TAF-based fixed dose combination that were illegally protected from competition;

c. Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected fixed dose combination;

d. Abusing the regulatory process by withholding an HIV indication from standalone TAF to raise rivals' costs and delay their entry into the market; and

e. Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

399. To the extent that Defendants are permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for Defendants' conduct comprising the anticompetitive scheme that outweighs its harmful effects. Even if there were some conceivable such justification that Defendants were permitted to assert, the scheme is and was broader than necessary to achieve such a purpose.

400. Plaintiff and Class Members have been injured in their business or property by the violation of 15 U.S.C. §§ 1, 2. Plaintiff and Class Members' injury consists of having paid higher prices for its cART drug regimen requirements than it would have paid in the absence of those violations. Such injury, called "overcharges," is of the type that the antitrust laws were designed

to prevent, and it flows from that which makes the defendants' conduct unlawful. KPH, as an assignee of direct purchaser McKesson Corporation, is a proper entity to bring a case concerning this conduct.

401. Plaintiff and Class Members have been injured, and unless Defendants' unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Defendants' continuing conspiracy in violation of Sections 1 and 2 of the Sherman Act.

COUNT 2 – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 AGAINST GILEAD

402. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

403. At all relevant times, Gilead has possessed substantial market power (i.e., monopoly power) in the cART Market and narrower markets therein. More than 80% of patients starting an HIV regimen in the United States, and more than 80% of continuing patients, take one or more of Gilead's products every day. Gilead possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the cART Market.

404. That market power is coupled with strong regulatory and contractual barriers to entry into the cART Market.

405. As alleged extensively above, Gilead willfully maintained its monopoly power in the cART Market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class Members.

406. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

407. As stated more fully above, Gilead knowingly, willfully, and wrongfully maintained its monopoly power and harmed competition by:

a. Entering into and abiding by the illegal No-Generics Restraints;

b. Degrading Stribild and artificially raising its price to drive patients to TAF-based fixed dose combination that were illegally protected from competition;

c. Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected fixed dose combination;

d. Abusing the regulatory process, by withholding an HIV indication from standalone TAF, to raise rivals' costs and delay their entry into the market; and

e. Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

408. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully maintain Gilead's monopoly power, which harms the competitive process and purchasers, in violation of Section 2 of the Sherman Act.

409. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable such justification that Gilead were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

410. Plaintiff and Class Members have been injured, and unless Gilead's unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Gilead's continuing monopolization in violation of Section 2 of the Sherman Act.

COUNT 3 – ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2 AGAINST GILEAD

411. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

412. At all relevant times, Gilead possessed substantial market power (i.e., monopoly power), or possessed a dangerous probability of achieving monopoly power, in the cART Market and narrower markets therein.

413. With the specific intent to achieve a monopoly, Gilead attempted to acquire and/or willfully maintain monopoly power in the cART Market by means of restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class Members.

414. Gilead's conscious objective was to further its dominance in the cART Market by and through its exclusionary conduct.

415. As stated more fully above, Gilead knowingly, willfully, and wrongfully attempted to acquire and/or maintain monopoly power by:

a. Entering into and abiding by the illegal No-Generics Restraints;

b. Degrading Stribild and artificially raising its price in order to drive patients to TAF-based fixed dose combination that were illegally protected from competition;

c. Degrading standalone TAF, also in furtherance of the scheme to drive patients to the illegally protected fixed dose combination;

d. Abusing the regulatory process, by withholding an HIV indication from standalone TAF, in order to raise rivals' costs and delay their entry into the market; and

e. Causing delayed entry of generic versions of Viread, Truvada, and Atripla.

416. Gilead's anticompetitive conduct identified above is exclusionary conduct the purpose and effect of which is to willfully attempt to acquire and/or maintain monopoly power through exclusionary means, in violation of Section 2 of the Sherman Act.

417. To the extent that Gilead is permitted to assert one, there is and was no cognizable, non-pretextual procompetitive justification for its exclusionary conduct that outweighs that conduct's harmful effects. Even if there were some conceivable such justification that Gilead

were permitted to assert, the conduct is and was broader than necessary to achieve such a purpose.

418. Plaintiff and the Class Members have been injured, and unless Gilead's unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Gilead's continuing attempt to monopolize in violation of Section 2 of the Sherman Act.

COUNT 4 – CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 AGAINST GILEAD AND JANSSEN

419. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

420. Gilead and Janssen have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by: (a) agreeing to and abiding by the No-Generics Restraints with respect to Complera, Odefsey, Prezcobix, and Symtuza; (b) agreeing that, and abiding by the agreement that, in exchange for Janssen's providing a No-Generics Restraint with respect to Odefsey, Gilead would provide a No-Generics Restraint with respect to Prezcobix and Symtuza; and (c) agreeing to and abiding by mutual No-Generics Restraints with respect to Symtuza. By entering into these unlawful agreements, Gilead and Janssen unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and Janssen are horizontal market allocation agreements between actual or potential competitors and are illegal per se. Alternatively, and at a minimum, they are unreasonable restraints of trade in violation of Section 1.

421. Plaintiff and Class Members have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff and Class Members have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic or comparable alternative for their purchases of the more expensive brand and/or the more expensive generic

products.

422. As a result of Defendants' unlawful conduct, Plaintiff and Class Members paid more than they would have paid for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Complera, Odefsey, Prezista, Prezcobix, Edurant, Symtuza, and competing cART drugs absent that unlawful conduct. But for Gilead and Janssen's unlawful conduct, competitors would have begun marketing generic or comparable versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

423. If Gilead and Janssen had competed in a full and timely fashion, Plaintiff and Class Members would have substituted lower-priced generic or comparable products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining purchases, and/or would have received a superior product for the purchases that they made.

424. During the relevant period, Plaintiff and Class Members purchased substantial amounts of the products. As a result of Gilead and Janssen's unlawful conduct, Plaintiff and the Class Members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff and Class Members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiff and Class Members were deprived of the opportunity to purchase lower-priced generic and comparable products instead of expensive brand products; (2) Plaintiff and Class Members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and Janssen's conduct.

425. Plaintiff and Class Members have been injured, and unless Defendants' unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Gilead

and Janssen's continuing conspiracy in violation of Section 1 of the Sherman Act.

COUNT 5 – CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 AGAINST GILEAD AND JAPAN TOBACCO

426. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

427. Gilead and Japan Tobacco have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics Restraints with respect to Stribild and Genvoya, the purpose and effect of which was to impair competition. By entering into these unlawful agreements, Gilead and Japan Tobacco unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and Japan Tobacco are horizontal market allocation agreements between actual or potential competitors and are illegal per se.

428. Alternatively, and at a minimum, they are unreasonable restraints of trade in violation of Section 1.

429. Plaintiff and Class Members have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff and Class Members have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic or comparable alternative for their purchases of the more expensive brand and/or the more expensive generic products.

430. As a result of Defendants' unlawful conduct, Plaintiff and Class Members paid more than they would have paid for Viread, Emtriva, Tybost, Vemlidy, Truvada, Descovy, Stribild, Genvoya, and competing cART drugs absent that unlawful conduct. But for Gilead and Japan Tobacco's unlawful conduct, competitors would have begun marketing generic or

comparable versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

431. If Gilead and Japan Tobacco had competed in a full and timely fashion, Plaintiff and Class Members would have substituted lower-priced generic or comparable products for the higher- priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining purchases, and/or would have received a superior product for the purchases that they made.

432. During the relevant period, Plaintiff and Class Members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and Japan Tobacco's unlawful conduct, Plaintiff and Class Members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff and Class Members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiff and Class Members were deprived of the opportunity to purchase lower-priced generic or comparable products instead of expensive brand products; (2) Plaintiff and Class Members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and Japan Tobacco's conduct.

433. Plaintiff and Class Members have been injured, and unless Defendants' unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Gilead and Japan Tobacco's continuing conspiracy in violation of Section 1 of the Sherman Act.

COUNT 6 – CONSPIRACY IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1 AGAINST GILEAD AND BMS

434. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

435. Gilead and BMS have engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade by agreeing to and abiding by the No-Generics Restraints with respect to Atripla and Evotaz the purpose and effect of which was to impair competition. By entering into these unlawful agreements, Gilead and BMS unlawfully conspired in restraint of trade and violated Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements between Gilead and BMS are horizontal market allocation agreements between actual or potential competitors and are illegal per se.

436. Alternatively, and at a minimum, they are unreasonable restraints of trade in violation of Section 1.

437. Plaintiff and Class Members have been injured in their business and property by reason of the unlawful contracts, combinations, and/or conspiracies. Plaintiff and Class Members have paid more on their purchases of the brand and generic products than they would otherwise have paid, and/or were prevented from substituting a less expensive, generic alternative for their purchases of the more expensive brand and/or the more expensive generic products.

438. As a result of Defendants' unlawful conduct, Plaintiff and Class Members paid more than they would have paid for Viread, Emtriva, Truvada, Atripla, Tybost, Reyataz, Evotaz, and competing cART drugs absent that unlawful conduct. But for Gilead and BMS's unlawful conduct, competitors would have begun marketing generic versions of the brand products much sooner than they did and/or would have been able to market such versions more successfully.

439. If Gilead and BMS had competed in a full and timely fashion, Plaintiff and Class Members would have substituted lower-priced generic products for the higher-priced brand products for some or all of their brand purchases, would have paid lower prices on some or all of their remaining brand and/or generic purchases, and/or would have received a superior product for the purchases that they made.

440. During the relevant period, Plaintiff and Class Members purchased and/or reimbursed for substantial amounts of the products. As a result of Gilead and BMS's unlawful conduct, Plaintiff and Class Members were compelled to pay, and did pay, artificially inflated prices for their brand and generic products. Plaintiff and Class Members paid prices for their brand and generic products that were substantially greater than the prices they would have paid absent the unlawful conduct alleged herein because: (1) Plaintiff and Class Members were deprived of the opportunity to purchase lower-priced generic products instead of expensive brand products; (2) Plaintiff and Class Members were forced to pay artificially inflated prices for the brand products; and/or (3) the product was inferior to what it would have been absent Gilead and BMS's conduct.

441. Plaintiff and Class Members have been injured, and unless Defendants' unlawful conduct is enjoined, will continue to be injured in their business and property as a result of Gilead and BMS's continuing conspiracy in violation of Section 1 of the Sherman Act.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Members of the Direct Purchaser Class pray for relief as set forth below:

A. Certification of the Direct Purchaser Class pursuant to Federal Rule of Civil Procedure 23 and appointment of Plaintiff as Class Representative for the Direct Purchaser Class;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust laws and requires it to take affirmative steps to dissipate the effects of the violations;

C. That acts alleged herein be adjudged and decreed to be an unlawful conspiracy to monopolize in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 as alleged in Count 1;

D. That acts alleged herein be adjudged and decreed to be unlawful monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, as alleged in Count 2;

E. That acts alleged herein be adjudged and decreed to be unlawful attempted monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, as alleged in Count 3;

F. That acts alleged herein be adjudged and decreed to be an unlawful conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, as alleged in Count 4;

G. That acts alleged herein be adjudged and decreed to be an unlawful conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, as alleged in Count 5;

H. That acts alleged herein be adjudged and decreed to be an unlawful conspiracy in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, as alleged in Count 6;

I. Enter joint and several judgments against Defendants for the damages sustained by Plaintiff and the Direct Purchaser Class defined herein and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

J. By awarding Plaintiff and Members of the Direct Purchaser Class pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the complaint in this action;

K. The costs of this suit, including reasonable attorney fees; and

L. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: February 5, 2020

Respectfully submitted,

By: /s/ Michael L. Roberts

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